CITIZEN PETITION

Date: June 1, 2015

The undersigned submit this Petition pursuant to 21 CFR 10.25(a)(2) and under 21 USC 393(b) and other applicable statutes to request the Commissioner of Food and Drugs to issue the regulation described in Part A.

A. ***Action Requested – Proposed Regulation***

Issue a regulation in 21 CFR Part 250 (or in another appropriate Part) in substantially the following form:

(a) Fluoridation chemical additives (whether or not certified under NSF/ANSI Standard 60) and fluoridated drinking waters (bottled and/or from public water systems, that are fluoridated with such additives) are drugs pursuant to section 201(g)(1) of the Federal, Food, Drug, and Cosmetic Act (21 USC 321(g)(1)) when the intended use is to aid in the prevention, mitigation, and/or prophylactic treatment of dental caries disease (tooth decay, cavities).

(b) Fluoridation chemical additives include:

(1) Fluorosilicic Acid (aka Fluosilicic Acid or Hydrofluosilicic Acid).
(2) Sodium Fluorosilicate (aka Sodium Silicofluoride).
(3) Sodium Fluoride.
(4) Calcium Fluoride.

(c) It is presumed that the intended use of such additives and such fluoridated drinking waters is to aid in the prevention, mitigation, and/or prophylactic treatment of dental caries disease (tooth decay, cavities).

(d) The Food and Drug Administration has jurisdiction to ensure that uses of fluoridation chemical additive drugs are safe and effective.

B. ***Statement of Grounds***

1. <u>All Drinking Waters (bottled or public) are Drugs When They Include Fluoridation Chemical Additives to prevent, mitigate and/or prophylacticly treat tooth decay disease</u>

The Federal Food, Drug, and Cosmetic Act (FD&C Act) explicitly makes articles drugs when intended for use in the treatment, mitigation and/or prevention of disease:

> The term "drug" means
> (A) articles recognized in the official United States Pharmacopoeia . . .; and
> (B) **articles intended for use in the** diagnosis, cure, **mitigation, treatment, or prevention of disease in man** or other animals; and
> (C) articles (other than food) intended to affect the structure of any function of the body of man or other animals; and
> (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). . . .

(21 USC 321(g)(1); emphasis supplied.) The language quoted has not been amended since it was originally adopted in the 1938 Act. (52 Stat. 1041.)

It is well-known and broadly accepted that fluoridated water is intended to reduce [i.e. mitigate or treat] and prevent tooth decay disease. (76 FR 2383 at 2386.) Fluoridated water is drinking water (bottled or public) with fluoridation chemicals added. Nearly all states require fluoridation chemicals to be certified by NSF/ANSI Standard 60. Attachment 1 (Att. 1) hereto is page 1 of a 2008 Fact Sheet on Fluoridation Chemicals authored by NSF (formerly National Sanitation Foundation). It states that fluoridation chemicals are "added to water for the public health benefit of preventing and reducing tooth decay" and for no other reason. (Attachment 1 hereto.) It identifies the three basic fluoridation chemicals that NSF certifies as:

(1) Fluorosilicic Acid (aka Fluosilicic Acid or Hydrofluosilicic Acid).
(2) Sodium Fluorosilicate (aka Sodium Silicofluoride).
(3) Sodium Fluoride.

(Attachment 1 hereto.) A fourth fluoridation chemical that is added to drinking water by at least one city in the United States is Calcium Fluoride. These are the four fluoridation chemicals additives that are named in the proposed regulation.

Fluoridated waters qualify as drugs under the plain language of the Food Drug and Cosmetic Act because they are "intended for use in the mitigation, . . . treatment or prevention of disease." (21 USC 321(g)(1)(B).) Fluoridation chemical additives are drugs because they are "intended for use as a component," (as the active ingredient) of fluoridated waters. (21 USC 321(g)(1)(D).) Fluoridation chemical additives are also drugs because they, themselves, are "intended for use in the mitigation, . . . treatment or prevention of disease." (21 USC 321(g)(1)(B); Attachment 1 hereto.) Sodium fluoride is also a drug because it is "recognized in the official United States Pharmacopoeia." (21 USC 321(g)(1)(A).)

Because fluoridated waters and fluoridation chemical additives are well-known and widely accepted by the public as being intended for use in the mitigation, treatment and/or prevention of tooth decay disease, the proposed regulation creates a presumption that this is the intent of use of these articles.

Because fluoridated waters and fluoridation chemical additives are presumed drugs, the proposed regulation clarifies that FDA has jurisdiction to ensure that these additives are safe and effective in their manner of use pursuant to the FDA obligation in 21 USC 393(b).

2. Fluoridation Chemical Additives Are Drugs, Not Foods

Some argue that fluoridation chemical additives are dietary supplements and therefore they are foods and not drugs. But federal courts have ruled that if the intended use of a food falls within the definition of a drug (21 USC 321(g)(1)(B)), then the food is regulated as a drug. Interpretations of federal statutes by federal courts are entitled to great weight. A long line of federal court cases has found that articles normally regulated as "foods" shall be regulated as "drugs" if the intended use is to mitigate, treat and/or prevent a disease:

> The word "drug" is defined in 21 U.S.C. s 321(g)(1)(B) to include: articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals . . . Thus, it is the intended use of an article which determines whether or not it is a "drug," and even the most commonly ingested foods and liquids are "drugs" within the meaning of the [FD&C Act] if their intended use falls within the definition of s 321(g)(1)(B).

Gadler v. United States, 425 F.Supp. 244, 246-47 (D.Minn. 1977); *see* Nutrilab, Inc. v. Schweiker, 713 F.2d 335, 336 (7th Cir. 1983); *see also* Bradley v. United States, 264 F.79 (5th Cir., 1920) where the court specifically found "mineral water" to be a "drug" when it is intended to treat disease.

3. In 1994, Congress Clarified Why Fluoridation Chemical Additives Are Drugs

In 1994, Congress adopted the Dietary Supplement Health and Education Act of 1994 (Pub. L. 103-417; "DSHEA".) This 1994 Act of Congress clarified Congressional intent that mineral additives including fluorides are drugs if the intended use is to prevent disease:

> A dietary supplement is deemed to be " food," [21 USC] 321(ff), which is defined in part as "articles used for food or drink for man or other animals," *Id.* § 321(f)(1), except when it meets the definition of a "drug," which is defined in part as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals."

(Alliance for Natural Health U.S. v. Sebelius, 714 F.Supp.2d 48, 50 (D.D.C. 2010) (interpreting DSHEA (emphasis supplied)).) Under DSHEA, dietary supplements include minerals. (21 USC 321(ff)(1)(B).) Minerals under DSHEA are normally regulated as foods except when they qualify as drugs. (21 USC 321(ff) (postscript states "except for purposes of [21 USC 321(g)(1) which describes drugs] a dietary supplement shall be deemed to be a food.")) In the determination of whether fluoridation products are drugs:

> the only question under the [FD&C Act] is whether the intended use of the product is to prevent disease, not whether the product actually prevents disease.

(United States v. Bowen, 172 F.3d 682, 686 (9th Cir. 1999).) Intent "may be derived or inferred from [any] relevant source." (National Nutritional Foods Ass'n v. Mathews, 557 F.2d 325, 334 (2nd Cir. 1977).) As discussed previously, the "intended use" of fluoridation chemical additives is to mitigate, treat and/or prevent dental caries (tooth decay) disease. (*Supra* at 2-3.)

4. Congress Intended The FDA To Regulate The Addition Of Fluoride To Public Drinking Water For Dental Caries Prevention As A Drug Under The FD&C Act

Congress intended the FDA to regulate the addition of fluoride to public drinking water for dental caries disease prevention as a drug under the FD&C Act. Fluoridated waters with fluoridation chemical additives are drugs. The FDA has not identified anything in the FD&C Act that suggests otherwise. Under the FD&C Act, foods are regulated as drugs if the intended use is to mitigate, treat, and/or prevent disease. (*Supra* at 2-4.) Over the past few years, some in FDA

have argued that the Safe Drinking Water Act (42 USC 300f et seq.) relieves FDA of its jurisdiction to regulate fluoridation chemical additives and fluoridated waters as drugs. (Attachments 4A, 4B, and 4C and particularly 4A and 4C; Attachments 5-6; Attachments 7-9 and particularly 7-8, all hereto.) For the reasons given below, the FDA errs when it finds fluoridated waters and fluoridation chemical additives are not drugs.

(a) FDA Ruling on Dr. Eloise Kailin Request for Designation

Dr. Eloise Kailin proposed to use sodium fluoride to fluoridate a public water system she manages and she submitted a Request for Designation under the authority of 21 CFR 3.7(a)(2). (Attachments 9-23 hereto.) Dr. Kailin interpreted 21 CFR 3.7(a)(2) as allowing a determination as to whether CDER would have primary jurisdiction because the fluoridated water was intended to prevent dental caries disease. The Request was accepted by FDA as complete. The regulation states that a Request is allowed for, "Any product [including proposed drugs] where the agency component with primary jurisdiction is unclear or in dispute." 21 CFR 3.8(b) provides that if FDA does not respond in 60 days, Dr. Kailin's recommendation that CDER has primary jurisdiction must be accepted.

Dr. Kailin's request received a formal Commissioner briefing led by Jill Hartzler Warner, J.D. The decision by the FDA Office of Combination Products issued by Leigh Hayes states:

> We have determined that Congress did not intend for FDA to regulate the addition of fluoride to public drinking water for dental caries prevention as a drug under the Federal Food, Drug, and Cosmetic Act (FD&C Act). Instead, Congress intended that the U.S. Environmental Protection Agency (EPA) regulate fluoride in public drinking water as a potential contaminant under the Safe Drinking Water Act of 1974 (SDWA) to protect against adverse health effects, and that within the limits thus set by EPA, state and local governments be permitted, but not required, to fluoridate drinking water to help prevent dental caries. Thus, we are not designating your fluoridated drinking water as a drug under the FD&C Act.

(Attachment 4A hereto.)

In response to this decision, Dr. Kailin filed a Request for Review. (Attachments 2-4 and 4A-4C hereto.) Approximately two years later, Jill Hartzler Warner issued a response. (Attachment 5-6 hereto.) She states:

> I have carefully considered both the text and the legislative history of the SDWA, and I agree with OCP's determination that Congress did not intend for FDA to regulate the addition of fluoride to public drinking water for dental caries prevention as a drug under the FD&C Act.

(Attachment 5 hereto.) This same FDA argument was repeated in a November 21, 2014 HHS response to a request to enforce the FD&C Act on fluoridation chemical additive manufacturers. (Attachments 7-8 hereto.)

Thus, some in the FDA are interpreting the SDWA to conclude that the SDWA relieves FDA of any responsibility under the FD&C Act to ensure that drugs are safe and effective with respect to fluoridated drinking water. The legal error is that the authority to interpret the SDWA lies with the EPA as the agency with administrative authority. Dr. Kailin had submitted a letter from Steven Neugeboren with her Request. (Attachments 23-24 hereto.) Mr. Neugeboren speaks for the EPA Administrator on interpretation of the SDWA. (*Id.*) Mr. Neugeboren disagrees with FDA's interpretation of the SDWA. (*Id.*) Mr. Neugeboren states:

> Under the Safe Drinking Water Act (SDWA), EPA is the lead federal agency with responsibility to regulate the safety of public water supplies. EPA does not have responsibility for substances added to water solely for preventative health care purposes, such as fluoride, other than to the limit the addition of such substances [so Maximum Contaminant Levels are not exceeded]. The Department of Health and Human Services (HHS) acting though the FDA, remains responsible for regulating the addition of drugs to water supplies for health care purposes.

(Attachment 23 hereto.) Thus the EPA interprets the SDWA to not affect any authority that FDA has under the FD&C Act to ensure that drugs are safe and effective with respect to fluoridated drinking water. If the waters and fluoridation chemical additives meet the definition of drugs in the FD&C Act, then FDA has jurisdiction to ensure that these articles are safe and effective. FDA cannot legally rely on the SDWA to avoid its responsibilities under the FD&C Act. EPA, in effect, states there is no conflict in the SDWA that would affect FDA authority in the FD&C Act with respect to fluoridated drinking water. FDA, in its communications, has not identified any specific conflict between the SDWA and the FD&C Act. Without a conflict, each agency has the jurisdiction expressed in the statutes it administrates. If the statutory language is not ambiguous, the legislative history cannot be considered. FDA has not alleged that any specific statutes are ambiguous and yet the FDA states that it relies on legislative history of the SDWA without a identifying any specific conflict. (Attachments 5-6 hereto.) Should a conflict be identified, the next step is to harmonize conflicting language so that both statutes are implemented.

Given the recent actions by HHS (*see* 76 FR 2383 at 2386; 80 FR 24936) to recommend adding fluoride to public drinking water for prevention of dental caries disease, FDA should no longer argue that this fluoridation chemical additive is just a contaminant regulated by EPA. Instead it is an additive intended to make fluoridated waters that are intended to reduce and prevent tooth decay disease. Under the unambiguous definition of a drug in the FD&C Act, the FDA should find that both the fluoridated waters and the fluoridation chemical additives are drugs with FDA jurisdiction to make them safe and effective. Because finding fluoridated waters and fluoridation chemical additives to be drugs is a major change in FDA administrative policy, this policy change should be implemented by the proposed regulation in Part A of this Petition.

(b) FDA Ruling on Mike Libera Request for Designation

After the FDA decision was made that Dr. Kailin's fluoridated public water was not a drug allegedly because of unidentified text in the SDWA, Mike Libera submitted a Request for Designation to determine if his proposed bottled water with his proposed fluoridation chemical additives (including sodium fluoride) would be a drug if it was marketed with a label that states: "This drinking water is intended for use in the prevention of tooth decay disease." (Attachment 25-39, hereto.) The response from FDA was that it was unclear to FDA whether this product would be a drug because bottled water is generally regulated by the Center for Food Safety and Applied Nutrition (CFSAN) as a food. (Attachment 43.) The FDA response states that:

> Jurisdictional questions concerning a product that may be within the jurisdiction of the Center for Food Safety and Applied Nutrition (CFSAN) are outside the scope of 21 CFR Part 3 and section 563 [21 USC 360bbb-2] of the FD&C Act.

(*Id.*) The FDA refused to answer the question of whether the Libera bottled fluoridated water with an explicit "drug claim" would be a drug even though it acknowledged that it may be a drug. (*Id.*) Section 360bbb-2 of the FD&C Act explicitly states that a person "may submit a request to the Secretary respecting the classification of the product as a drug . . . or respecting the component of the Food and Drug Administration that will regulate the product." While this section does not authorize a determination of whether a product is a food, it does authorize a determination of whether a product is a drug and so FDA is required to answer that question.

Mike Libera filed a request for review of the decision refusing to make a determination of whether his product would be a drug. (Attachment 40-44 hereto.) The FDA upheld its determination that if a product may be a food, then it cannot determine if it is a drug under 21 CFR Part 3 and 21 USC 360bbb-2 of the FD&C Act. (Attachment 45-46 hereto.) This decision is inconsistent with the FDA response to the Request for Designation for the Kailin Public Drinking Water. (Attachments 4A to 4C and 5-6 hereto.) In that decision, despite the fact that

drinking water may be either a food or a drug, the FDA determined [erroneously] that fluoridated public drinking water is not a drug.

The proposed regulation in Part A of this Petition applies to both fluoridated public drinking water and fluoridated bottled water as well as the fluoridation chemical additives used to make these products. (*Supra* at 1.) It is necessary for the FDA to clearly address these issues in the proposed regulation so the public health will be protected.

5. Congress Did Not Intend To Make States And Local Government Responsible For Determining If Fluoridated Water And Fluoridation Chemical Additives, All In Interstate Commerce, Are Safe And Effective

Despite the Congressional mandate in 21 USC 393(b) that FDA ensure that drugs are safe and effective, and despite the unambiguous definitions of drugs in 21 USC 321(g)(1), some in the FDA and HHS state that Congress intended state and local governments to determine if fluoridated water and fluoridation chemical additives in interstate commerce are safe and effective when used to prevent dental caries disease. (*See* Attachments 5 and 8.) This is clearly beyond the abilities of most state and local governments and puts the citizens at the mercy of the fluoridation peddlers. The FDA was established by Congress, in part, to ensure that articles that meet the definition of drugs in 21 USC 321(g)(1), will not be marketed unless FDA has determined that they are safe and effective (pursuant to drug review standards). There is substantial evidence of harm of public water fluoridation and there is substantial evidence that public water fluoridation is ineffective.

As an example, Attachment 47 hereto shows a correlation of fluoridation prevalence with Attention-Deficit Hyperactivity Disorder (ADHD) in fifty states. This graph is adapted from Malin (2015) by adding color. (*See* http://www.ehjournal.net/content/14/1/17/abstract) This graph shows percent of children 4-17 medically-diagnosed with ADHD increases linearly with increases in percent of state population fluoridated. Fluoridation information is from CDC. ADHD rates are from the National Survey of Children's Health. Socioeconomic status is controlled. In 2011, 8.8 percent of children in non-fluoridated states were diagnosed with ADHD. This increased to 13.9 percent for fully-fluoridated states. This is a 58% increase. Child ADHD prevalence is linearly correlated with fluoridation prevalence with relatively little scatter. It is time to regulate fluoridated waters and fluoridation chemical additives as drugs under the jurisdiction of the FDA and we request that FDA adopt the regulation proposed in Part A of this Petition.

This Petition meets the requirements of 21 CFR 10.40(2) in that it contains facts demonstrating reasonable grounds for the proposal and the Petition substantially shows that the proposal is in the public interest and will promote the objectives of the FD&C Act and the FDA.

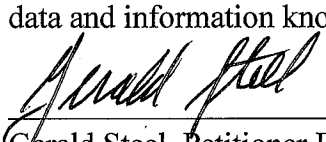
C. ***Environmental Impact***

FDA should find that this action is of type that does not individually or cumulatively have a significant effect on the human environment. This action has a categorical exclusion under 21 CFR 25.30(h) because it is an administrative regulation and under 21 CFR 25.32(m) because it should result in restrictions on or reductions in the use fluoridation chemical additives in drinking water which, when unfluoridated, is considered a food.

D. ***Economic Impact-Not Required***

E. ***Certification***

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioners which are unfavorable to the petition.



Gerald Steel, Petitioner Representative
360.867.1166

On Behalf Of:

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February 2008

NSF Fact Sheet on Fluoridation Chemicals

Introduction

This fact sheet provides information on the fluoride containing water treatment additives that NSF has tested and certified to NSF/ANSI Standard 60: Drinking Water Chemicals - Health Effects. According to the latest Association of State Drinking Water Administrators Survey on State Adoption of NSF/ANSI Standards 60 and 61, 45 states require that chemicals used in treating potable water must meet Standard 60 requirements. If you have questions on your state's requirements, or how the NSF/ANSI Standard 60 certified products are used in your state, you should contact your state's Drinking Water Administrator.

Water fluoridation is the practice of adjusting the fluoride content of drinking water. Fluoride is added to water for the public health benefit of preventing and reducing tooth decay and improving the health of the community. The U.S. Centers for Disease Control and Prevention is a reliable source of information on this important public health intervention. For more information please visit www.cdc.gov/fluoridation/.

NSF certifies three basic products in the fluoridation category:

1. Fluorosilicic Acid (aka Fluosilicic Acid or Hydrofluosilicic Acid).
2. Sodium Fluorosilicate (aka Sodium Silicofluoride).
3. Sodium Fluoride.

NSF Standard 60

Products used for drinking water treatment are evaluated to the criteria specified in NSF/ANSI Standard 60. This standard was developed by an NSF-led consortium, including the American Water Works Association (AWWA), the American Water Works Association Research Foundation (AWWARF), the Association of State Drinking Water Administrators (ASDWA), and the Conference of State Health and Environmental Managers (COSHEM). This group developed NSF/ANSI Standard 60, at the request of the US EPA Office of Water, in 1988. The NSF Joint Committee on Drinking Water Additives continues to review and maintain the standard annually. This committee consists of representatives from the original stakeholder groups as well as other regulatory, water utility and product manufacturer representatives.

Standard 60 was developed to establish minimum requirements for the control of potential adverse human health effects from products added directly to water during its treatment, storage and distribution. The standard requires a full formulation disclosure of each chemical ingredient in a product. It also requires a toxicology review to determine that the product is safe at its maximum use level and to evaluate potential contaminants in the product. The standard requires testing of the treatment chemical products, typically by dosing these in water at 10 times the maximum use level, so that trace levels of contaminants can be detected. A toxicology evaluation of test results is required to determine if any contaminant concentrations have the potential to cause adverse human health effects. The standard sets criteria for the establishment of single product allowable concentrations (SPAC) of each respective contaminant. For contaminants regulated by the U.S. EPA, this SPAC has a default level not to exceed ten-percent of the regulatory level to provide protection for the consumer in the unlikely event of multiple sources of the contaminant, unless a lower or higher number of sources can be specifically identified.

Att. 1

Gerald Steel PE
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December 23, 2013

Ms. Jill Warner,
Acting Assoc. Commissioner
WO32, Room 5162
10903 New Hampshire Ave
Silver Spring, MD 20993

RE: Request for Review pursuant to 21 CFR 10.75 – Kailin System Public Drinking Water with Sodium Fluoride – Your file: RFD130073

Dear Ms. Warner:

On September 27, 2013, Leigh Hayes sent me the FDA determination (Attachments A-1 to A-3 hereto) wherein FDA states that it has determined that "Congress did not intend for FDA to regulate the addition of fluoride to public drinking water for dental caries prevention as a drug under the Federal Food, Drug, and Cosmetic Act (FD&C Act)." As a consequence, FDA has responded to our Request for Designation (RFD130073) by finding that our proposed fluoridated public drinking water is not a drug under the FD&C Act. On December 4, 2013, Leigh Hayes informed me that we can request review under 21 CFR 10.75. We hereby submit a Request for Review under 21 CFR 10.75 of the determinations regarding RFD130073.

The FDA has a long history of protecting the public from unsafe and ineffective drugs. Generally, state and local governments do not have the capability or staff to determine if articles or substances intended for preventative health care purposes are safe and effective. HHS, generally acting through the FDA, is the only regulatory body that has the authority to implement the FD&C Act in interstate commerce and protect the public from such articles and substances that are not safe and effective. So we ask the FDA to review its determination that our proposed "fluoridated public drinking water" is not a drug under the FD&C Act.

I believe that the FDA has accepted our statement of facts as accurate. Sodium Fluoride, as a water additive certified under industrial ANSI/NSF Standard 60 is intended for use in the prevention of tooth decay disease in man. (RFD130073 – our RFD at pages 1 and A-1.) This chemical with this intended use is square within the literal language included in the definition of a drug by Congress in 21 USC 321(g)(1)(B). (RFD130073 – our RFD at page 6.) When this chemical is added to our public drinking water, this chemical retains its intended use (prevention of tooth decay disease in man). The purpose of adding this chemical to our public drinking water is to deliver this chemical in drinking water for its intended use. As we stated, our "fluoridated public drinking water" is "intended for use in the prevention of dental caries (tooth decay) disease in man." (RFD130073 – our RFD at page 1.) With this statement, our "fluoridated public drinking water" is square within the literal language included in the definition of a drug in 21 USC 321(g)(1)(B).

RFD130073 provided a letter signed by EPA Water Law Office Associate General Counsel Steven M. Neugeboren, which was sent to me in 2013 on behalf of the EPA Administrator, and

which states the EPA official position that, "The Department of Health and Human Services (HHS) acting through the FDA, remains responsible for regulating the addition of drugs to water supplies for health care purposes." (RFD130073 – our RFD at page A-8 to A-9.) In RFD130073, we also cited to the Federal Supreme Court ruling in *United States v. An Article of Drug . . . Bacto-Unidisk* (*Bacto-Unidisk*), 394 U.S. 784, 793-801, 89 S.Ct. 1410, 22 L.Ed.2d 726 (1969) which found that the definition of "drug" in 21 USC 321(g)(1)(B) is "as broad as its literal language indicates." (RFD130073 – our RFD at page 6.) There can be no doubt that under the facts presented, ANSI/NSF Standard 60 certified Sodium Fluoride alone and our proposed fluoridated public drinking water are within the literal plain language of the definition of a drug in 21 USC 321(g)(1)(B). Therefore we continue to assert that such Sodium Fluoride and the proposed fluoridated public drinking water are drugs under federal law and are under the jurisdiction of FDA CDER.

I think we can assume that in 1974 Congress was aware of the definition of "drug" in 21 USC 321(g)(1)(B) and aware of the 1969 federal Supreme Court ruling in *Bacto-Unidisk*. I find no plain language in the 1974 SDWA (as amended) that seeks to carve out an exemption from the plain language of 21 USC 321(g)(1)(B) for fluoride water additives or fluoridated public drinking water when the intended use is for the prevention of dental caries disease in man. The challenged determination incorrectly claims that the "text" of the SDWA includes such [plain] language. It does not. The challenged determination also incorrectly claims support from the legislative history of the SDWA. The legislative history of the SDWA cannot be used by FDA to modify the plain language definition of "drug" in 21 USC 321(g)(1)(B) or modify the *Bacto-Unidisk* Court's interpretation of that drug definition. We request that you reverse the determination made for RFD130073 because the SDWA does not carve out an exemption from the plain language of 21 USC 321(g)(1)(B).

We claim that the intent of Congress is clear in 21 USC 321(g)(1)(B) as interpreted by *Bacto-Unidisk* that under our facts, ANSI/NSF Standard 60 certified Sodium Fluoride alone and our proposed fluoridated public drinking water are drugs under the FD&C Act. To further support our claim, we cited to 21 USC 321ff ("Dietary Supplement Health and Education Act of 1994") that states that minerals [such as fluoride public water additives] are foods except when they meet the definition of a drug. (RFD130073 – our RFD at page 6.) This 1994 statute did not exempt minerals that meet the definition of a "drug" in 21 USC 321(g)(1)(B) from being drugs just because the minerals were being added to public water supplies. This subsequent Congressional enactment supports our claim.

The federal Supreme Court in *FDA v. Brown & Williamson Tobacco Corp.* (*Tobacco Corp.*), 529 U.S. 120, 120 S.Ct. 1291, 146 L.Ed.2d 121 (2000) further supports our claim and refutes the claim in the determination regarding Congressional intent of 21 USC 321(g)(1)(B). The *Tobacco Corp.* Court found that reading the FD&C Act as a whole, as well as in conjunction with Congress' subsequent tobacco-specific legislation, it is plain that Congress has not given the FDA the authority to regulate tobacco products as customarily marketed. (*Tobacco Corp.* at 120 and 131-61.) "As customarily marketed" means "without manufacturer claims of therapeutic benefit." (*Id.* at 120.) But the *Tobacco Corp.* Court found that while the FDA did not generally have authority to regulate tobacco under the FD&C Act, there was a "well-established exception of when the manufacturer makes express claims of therapeutic benefit." (*Id.* at 158.) Therapeutic benefit refers to uses identified in 21 USC 321(g)(1)(B). We are making an express claim of therapeutic benefit for our proposed fluoridated public drinking water.

In the instant case, Congress has not shown that it has created a distinct regulatory scheme addressing the subject of purposely adding fluoride to public drinking water. But even if it did

Att. 3

have such a distinct regulatory scheme, FDA still has authority and responsibility under the FD&C Act to regulate fluoride added to public drinking water when it is added for the "therapeutic benefit" of preventing tooth decay disease. Similarly, FDA has authority and responsibility under the FD&C Act to regulate our fluoridated public drinking water because our water is fluoridated with the intent to prevent tooth decay disease. The FDA can point to no relevant federal caselaw where products that are intended for use in the prevention of disease in man are not regulated by the FD&C Act independent of other Congressional enactments.

Therefore under 21 CFR 10.75(a)(3) and 21 CFR 10.75(c)(1) and (2) along with 21 CFR 10.75(d) we request review and if it is concluded that our proposed ANSI/NSF Standard 60 fluoride water additives and our proposed fluoridated public drinking water are drugs, we again request that you designate our proposed fluoridated public drinking as a drug regulated by CDER.

Respectfully submitted,

Gerald Steel, PE, Attorney at Law
geraldsteel@yahoo.com

Attachments: A-1 to A-3

Att. 4

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Office of Combination Products
WO 32, Room 5129
10903 New Hampshire Avenue
Silver Spring, MD 20993

September 27, 2013

Eloise Kailin
Owner and Manager
Gerald Steel
Attorney
Kailin Public Water System
160 Kane Lane
Sequim, WA 98382

Re: Request for Designation
Kailin Public Drinking Water System with Sodium Fluoride
Our file: RFD130073
Dated: July 22, 2013
Received: July 23, 2013
Filed: July 29, 2013

Dear Dr. Kailin and Mr. Steel:

The United States (U.S.) Food and Drug Administration (FDA) has completed its review of the request for designation (RFD) for the Kailin Public Drinking Water System with Sodium Fluoride that you submitted on behalf of Kailin Public Water System. We have determined that Congress did not intend for FDA to regulate the addition of fluoride to public drinking water for dental caries prevention as a drug under the Federal Food, Drug, and Cosmetic Act (FD&C Act). Instead, Congress intended that the U.S. Environmental Protection Agency (EPA) regulate fluoride in public drinking water as a potential contaminant under the Safe Drinking Water Act of 1974 (SDWA) to protect against adverse health effects, and that within the limits thus set by EPA, state and local governments be permitted, but not required, to fluoridate drinking water to help prevent dental caries. Thus, we are not designating your fluoridated public drinking water as a drug under the FD&C Act.

A-1
Att. 4A

Description

In your RFD, you seek designation of your specific public fluoridated drinking water as a drug under the FD&C Act. You assert that you will submit a New Drug Application (NDA) for your fluoridated public drinking water that "will be composed of our public drinking water with an added fluoridation product certified to meet ANSI/NSF Standard 60...: Sodium Fluoride with a maximum addition of 2.3 mg/L....The public drinking water system is registered with the Washington State Department of Health as PWS ID# AC982. It is a neighborhood system with multiple approved connections. The source water comes from a well as is typical for public water systems in Washington State and currently there is a transmission pipeline from the well to a tank that maintains water pressure for the system in an acceptable range. A distribution system which starts at the tank serves all of the individual residential and commercial connections. There are pressure zones in the distribution system where pressure reducers are used to lower water pressure for connections at lower elevations. All individual connections to the distribution system are made in a manner approved by the Washington State Department of Health."

The RFD explains that "...the transmission line will be rerouted to a small fluoridation building where fluoridation will occur and the fluoridated water will be transmitted to the tank that maintains water pressure. This public water system is required to meet standard specifications for public water systems in Washington State as established by the Washington State Board of Health." The RFD states that the addition of the fluoridation materials "...will be metered into flowing water in a manner to maintain the specified chemical concentration rates. The Sodium Fluoride will be injected using an up-draft fluoride saturator. The injection rate into the transmission line in the control house will be controlled using a 4 to 20 milliamperes signal from the main water meter so that finished fluoridation levels are close to 0.7 mg/L. Fluoride levels will be manually checked twice daily." Finally, with regard to packaging of the product, the RFD asserts that "[t]his system does not have conventional packaging. [The company proposes] that [it] will negotiate with CDER regarding adequate labeling. For example, [the company] will propose that drug facts and warning approved by CDER will be sent out with each billing for each connection."

You recommend that your fluoridated public drinking water designed to aid in the prevention and prophylactic treatment of dental caries disease be classified as a drug and that it be assigned to FDA's Center for Drug Evaluation and Research (CDER) for premarket review and regulation.

Product Classification

We have considered the information in the RFD and discussed the issues with staff from CDER, the Center for Food Safety and Applied Nutrition, the Department of Health and Human Services, HHS's Office of the General Counsel, and the EPA.

A-2
Att. 4B

After careful consideration, we conclude that Congress did not intend for FDA to regulate the addition of fluoride to public drinking water for dental caries prevention as a drug under the FD&C Act. Instead, Congress intended that EPA regulate fluoride in public drinking water as a potential contaminant under the SDWA to protect against adverse health effects, and that within the limits thus set by EPA, state and local governments be permitted, but not required, to fluoridate public drinking water to help prevent dental caries. The SDWA gives EPA certain authorities with respect to the regulation of public drinking water, including the authority to promulgate national primary drinking water regulations that set maximum contaminant levels (MCLs) for contaminants that EPA determines may have an adverse effect on human health. Pursuant to its authority under the SDWA, EPA has codified a primary MCL for fluoride at 40 CFR § 141.62(b)(1) and a secondary MCL for fluoride at 40 CFR § 143.3.

The historical context surrounding the passage of the SDWA indicates that Congress was aware in 1974 that many localities were adding fluoride to public drinking water to help prevent dental caries. They were also aware that FDA had a codified policy of not regulating such fluoride as a drug, so long as the levels were within certain recommended limits. Based on the text and legislative history of the SDWA, we have concluded that Congress did not intend for FDA to regulate fluoride in public drinking water for the purpose of helping to prevent dental caries as a drug under the FD&C Act. Instead, Congress set up a regime under which EPA would set upper limits for fluoride to protect against adverse health effects, and EPA would not have the authority to mandate or ban the use of fluoride to help prevent dental caries. The decision of whether or not to add fluoride to public drinking water to help prevent dental caries (within the limits set by EPA) was left to state and local authorities, as it had been before 1974. Since the passage of the SDWA, this division of federal and state/local oversight has continued.

Conclusion

For the reasons explained above, we have determined that Congress did not intend for FDA to regulate fluoride in public drinking water to help prevent dental caries as a drug under the FD&C Act, and we therefore are not designating your fluoridated public drinking water as a drug.

If you have any other questions about this letter, please feel free to contact me. You may reach us at the above address or by email at combination@fda.gov.

Sincerely,

Leigh Hayes

Leigh Hayes
Product Assignment Officer

A-3
Att. 4C

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-002

Thursday March 26, 2015

Mr. Gerald Steel PE
Attorney at Law
7303 Young Road, NW
Olympia WA 98502
(360) 867-1166

Re: Kailin System Public Drinking Water with Sodium Fluoride
Request for Designation (RFD), Office of Combination Products
FDA file: RFD 130073
Request for Review under 21 CFR 10.75

Dear Mr. Steel:

This letter is in response to your Request for Review under 21 CFR 10.75 for Kailin System Public Drinking Water with Sodium Fluoride (RFD130073) ("10.75 Request") dated December 23, 2013. You are appealing a September 27, 2013, determination by the Food and Drug Administration's (FDA) Office of Combination Products (OCP) not to designate your fluoridated public drinking water product as a drug under the under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

I have reviewed your 10.75 Request and the administrative file for the decision regarding your request. In your request, you argue that FDA has the authority to regulate chemicals that are added by state and local authorities to public drinking water supplies "for preventative health care purposes" as drugs.

I note that OCP's September 27, 2013, determination only applies to fluoridated public drinking water; accordingly, I am not addressing your arguments about FDA's authority to regulate other chemicals that may be added to public drinking water. With respect to fluoridated public drinking water, I find your argument regarding the Safe Drinking Water Act of 1974 (SDWA) to be unpersuasive. I have carefully considered both the text and the legislative history of the SDWA, and I agree with OCP's determination that Congress did not intend for FDA to regulate the addition of fluoride to public drinking water for dental caries prevention as a drug under the FD&C Act. Instead, Congress intended that the U.S. Environmental Protection Agency (EPA) regulate fluoride in public drinking water as a potential contaminant under the SDWA to protect against adverse health effects, and that within the limits thus set by EPA, state and local governments be permitted, but not required, to fluoridate public drinking water to help prevent dental caries.

Att. 5

Finally, I also find your argument regarding *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000) (*Brown & Williamson*), unpersuasive. *Brown & Williamson,* which addressed the regulation of products made or derived from tobacco, did not address the SDWA or the federal regulation of fluoridated public drinking water.

Therefore, I affirm OCP's determination that Congress did not intend for FDA to regulate the addition of fluoride to public drinking water for dental caries prevention as a drug under the FD&C Act. Accordingly, I affirm OCP's decision not to designate your fluoridated public drinking water as a drug under the FD&C Act.

Sincerely,

Jill Hartzler Warner, J.D.
Associate Commissioner for
Special Medical Programs

cc: Thinh Nguyen

Att. 6

NOV 21 2014

Dear Ms. McElheney:

Thank you for your correspondence concerning fluoridation of drinking water. Your letter requests that I take a number of actions related to fluoridation. These include instructing the Food and Drug Administration (FDA) to advise fluoridation manufacturers to submit New Drug Applications; instructing the Centers for Disease Control and Prevention (CDC) to stop "promotion. . . . of any and all drugs, including the ingestion of fluoride products, not FDA CDER approved"; sponsoring a review of fluoride's neurotoxicity by the National Research Council; and supporting a prospective randomized control trial of the effectiveness of ingesting hydrofluorosilicic acid.

For nearly 70 years, community water fluoridation (CWF) has been a safe and healthy way to effectively prevent tooth decay. CDC has recognized water fluoridation as one of ten great public health achievements of the 20th century. CDC works with national partners, states, communities, and water operators to ensure that the U.S. population has access to optimally fluoridated water to prevent tooth decay.

However, fluoride ingestion while teeth are developing can result in a range of visually detectable changes in the tooth enamel, called dental fluorosis. The prevalence of mild to moderate dental fluorosis in the United States has increased in recent years. Fluoride in drinking water is one of several available fluoride sources. In 2011, the Department of Health and Human Services (HHS) proposed that the recommended level of fluoride in drinking water be set at 0.7 mg/L. This will reduce the chance for children's teeth to develop dental fluorosis, while still preventing tooth decay. The previous U.S. Public Health Service recommendations for fluoride levels ranged from 0.7mg/L to 1.2 mg/L, depending on average maximum regional air temperature. The new recommendation is based on recent findings that in the U.S., outdoor temperature does not determine water intake.

HHS expects that the final recommendations to reduce the optimal fluoride level will be publicly available soon. CDC, in collaboration with the National Institute of Dental and Craniofacial Research (NIDCR), will monitor the impact of these changes through enhanced surveillance of dental caries (tooth decay) and dental fluorosis in the National Health and Nutrition Examination Survey (NHANES).

Your specific requests are addressed below.

Instruct FDA CDER to no longer defer regulatory action. FDA CDER to send a letter to fluoridation manufacturers advising them to make FDA CDER NDA (New Drug Application) as required by Congress in the US FD&C Act.

FDA has provided the following information regarding your request:

> *FDA has determined that Congress did not intend for FDA to regulate the addition of fluoride to public drinking water for dental caries prevention as a drug under the FD&C Act. Instead, Congress intended that the U.S. Environmental Protection Agency (EPA) regulate fluoride in public drinking water as a potential contaminant under the Safe Drinking Water Act of 1974 (SDWA), Public Law No. 93-523, 88 Stat. 1660 (codified as amended at 42 U.S.C. 300f et seq.) to protect against adverse health effects, and that within the limits thus set by EPA, state and local governments be permitted, but not required, to fluoridate public drinking water to help prevent dental caries. Thus, FDA does not require NDAs for fluoridated public drinking water.*

Instruct the CDC to stop the promotion (internet and education) of any and all drugs, including the ingestion of fluoride products, not FDA CDER approved.

Section 317M of the Public Health Service Act, codified at 42 U.S.C. § 247b-14, authorizes the Secretary of HHS, acting through the Director of the CDC, to make grants to States and Indian tribes for the purpose of increasing the resources available for community water fluoridation. This includes funds to develop educational materials on the benefits of fluoridation. CDC's Division of Oral Health leads an effort to improve the oral health of the nation and reduce inequalities in oral health. This includes encouraging the use of proven strategies to prevent oral disease, such as the effective use of fluoride products and community water fluoridation.

Sponsor a review of the scientific evidence on fluoride's neurotoxicity by the National Academy of Science's National Research Council. The review should include studies listed at www.FluorideAlert.org/issues/health/brain.

The NRC reviewed the toxicity of fluoride as recently as 2006, when it reviewed the Environmental Protection Agency's drinking water standard for fluoride as a contaminant. (See *Fluoride in Drinking Water: A Scientific Review of EPA's Standards.*) More recently and of more relevance to community water fluoridation is the systematic review undertaken by the Community Preventive Services Task Force (Task Force) in 2013. The Task Force is an independent, nonfederal, unpaid panel of public health and prevention experts that provides evidence-based findings and recommendations about community preventive services, programs, and policies to improve health. Its members represent a broad range of research, practice, and policy expertise in community preventive services, public health, health promotion, and disease prevention. In its report, *Preventing Dental Caries: Community Water Fluoridation*, the Task Force noted, "Overall, the body of evidence indicates that Community Water Fluoridation is an effective intervention for reducing caries at the population level. At the optimal fluoride concentration, associated risks are predominantly the milder forms of fluorosis that are only detectable under clinical examination." The report further stated, "In addition, there is no evidence that CWF (Community Water Fluoridation) results in severe dental fluorosis."

Sponsor a quality published independent prospective randomized controlled trial (RTC), of the effectiveness of ingesting hydrofluorosilicic acid (fluoridation), including blood serum and urine concentrations of fluoride.

Att. 8

As stated above, the effectiveness and safety of community water fluoridation was reaffirmed by the Community Preventive Services Task Force in 2013 following a systematic evidence review. Studies on the effectiveness of adjusting fluoride in community water to the optimal concentration cannot be designed as randomized clinical trials. Random allocation of study subjects is not possible when a community begins to fluoridate the water because all residents receiving community water have access to and are exposed to this source of fluoride. Furthermore, clinical studies cannot be conducted double-blind because both study subjects and researchers usually know whether a community's water has been fluoridated. In addition, it would not be possible to find control subjects with no fluoride exposure because fluorides are ubiquitous in the environment.

Although I am not able to fulfill your requests, I appreciate the information you provided to me and my staff. I will keep your concerns in mind as HHS continues to consider community water fluoridation.

A copy of this response is being shared with Dr. Hirzy, Mr. Nidel, Dr. Connett, Ms. Smith, and Dr. Osmunson.

Sincerely,

Wanda K. Jones, DrPH
Principal Deputy Assistant Secretary for Health

Att. 9

Gerald Steel PE
Attorney at Law
7303 Young Rd. NW
Olympia WA 98502
360.867.1166 Phone

July 22, 2013

Product Jurisdiction Officer
Food and Drug Administration
10903 New Hampshire Ave
Bldg. 32, rm. 5129
Silver Spring, MD 20993-0002

RE: 21 CFR 3.6 § 3.7. Request for Designation – Kailin System Public Drinking Water with Sodium Fluoride

Dear Product Jurisdiction Officer:

I hereby submit an original and two copies of this Request for Designation under the authority of 21 CFR § 3.7(a)(2).

Information provided pursuant to 21 CFR § 3.7 (c):

(1) The identity of the sponsor, including company name and address, establishment registration number, company contact person and telephone number.

The sponsor is: Kailin Public Water System
160 Kane Ln.
Sequim, WA 98382

There is no establishment registration number at this time.
The contact persons and telephone numbers are:
Eloise Kailin, Owner and Manager 360.683.6644
Gerald Steel, Attorney 360.867.1166

(2) Description of the product:

(i) Classification, name of the product and all component products, if applicable:

The product is fluoridated public water intended for use in the prevention of dental caries (tooth decay) disease in man. It will be composed of our public drinking water with an added fluoridation product certified to meet ANSI/NSF Standard 60 and used with the intent of preventing tooth decay disease: Sodium Fluoride with a maximum addition of 2.3 mg/L. *See* Attachments A-1 and A-2 hereto from the NSF Fact Sheet on certified Fluoridation Chemicals. The public drinking water system is registered with the Washington State Department of Health as PWS ID# AC982. It is a neighborhood system with multiple approved connections. The source water comes from a well as is typical for public water systems in Washington State and currently there is a transmission pipeline from the well to a tank that maintains water pressure for the system in an acceptable range. A distribution system which starts at the tank serves all of the individual residential and commercial connections. There are pressure zones in the distribution

Att. 10

system where pressure reducers are used to lower water pressure for connections at lower elevations. All individual connections to the distribution system are made in a manner approved by the Washington State Department of Health. To install the fluoridation system described below in subsection (2)(vii), the transmission line will be rerouted to a small fluoridation building where fluoridation will occur and the fluoridated water will be transmitted to the tank that maintains water pressure. This public water system is required to meet standard specifications for public water systems in Washington State as established by the Washington State Board of Health. We are submitting this request for designation prior to submitting an application for premarket review. This system does not have conventional packaging. We propose that we will negotiate with CDER regarding adequate labeling. For example, we will propose that drug facts and warning approved by CDER will be sent out with each billing for each connection.

(ii) Common, generic, or usual name of the product and all component products:

The common name is fluoridated public water or artificially fluoridated public water. The common name of the fluoridation chemical is listed in subsection (2)(i) above.

(iii) Proprietary name of the product:

There is no proprietary name of the product at this time.

(iv) Identification of any component of the product that already has received premarket approval, is marketed as not being subject to premarket approval, or has received an investigational exemption, the identity of the sponsors, and the status of any discussions or agreements between sponsors regarding the use of this product as a component of a new combination product.

Public drinking water without added Fluoridation Chemicals is properly marketed as not being subject to premarket approval by the FDA. To the best of our knowledge, all Fluoridation Chemicals are marketed without premarket approval by the FDA even though these products are intended for use in the prevention of disease in man. (*See* Attachment A-1, para. 2, hereto.) To the best of our knowledge, all Fluoridation Chemicals are certified to meet ANSI/NSF Standard 60. (*See* Attachments A-1 and A-2 hereto.) Names and addresses for the manufacturers of Fluoridation Chemicals that are certified to meet ANSI/NSF Standard 60 are found at http://www.nsf.org/Certified/PwsChemicals/Listings.asp?ProductFunction=Fluoridation& and http://www.wqa.org/goldseal/6.html There are 24 pages of additional listings by Underwriters Laboratories, Inc. that can be provided upon request. To the best of our knowledge, none of the Fluoridation Chemicals have received an investigational exemption. To the best of our knowledge, there are no other sponsors who have submitted or currently intend to submit an application to FDA for premarket review for fluoridated water. We have not yet held discussions with any of the manufacturers of Fluoridation Chemicals. If we must limit this request to a specific manufacturer of Sodium Fluoride, we limit it to the product described in Attachment A-7 hereto. However, we would prefer to not commit to any specific manufacturer at this time in order to minimize product costs.

In 1979, the EPA and FDA entered a Memorandum of Understanding ("MOU 225-79-2001"). This 1979 MOU is published in 44 FR 42775-78 (Vol. 44, No. 141 of the Federal Register (July 20, 1979) pages 42775-78 – provided in Attachments A-3 to A-6 hereto). Section II.A of this MOU gives the FDA legal authorities being negotiated in this MOU. (Section marked with "B" on Attachments A-3 and A-4 hereto.) The only FDA authorities being negotiated were "food" and "food additive" responsibilities. FDA drug responsibilities were not being negotiated and are

Att. 11

not covered by this MOU. This is confirmed by a recent letter from the EPA. Attachment A-8 and A-9 hereto.

(v) Chemical, physical, or biological composition:

The chemical composition is described in subsection (2)(i) above. Attachment A-7 hereto is a typical Certificate of Analysis for Sodium Fluoride. Any selected Sodium Fluoride will be certified to comply with ANSI/NSF Standard 60.

(vi) Status and brief reports of the results of developmental work, including animal testing:

Fluoridated water is being consumed today by a majority of people in the United States. Artificially fluoridated public water was first introduced in 1944. M. McDonagh et al., *A Systematic Review of Public Water Fluoridation* (NHS Centre of Reviews and Dissemination – University of York - 2000) (the "York Report") reviewed 3246 studies on public fluoridated water published between 1939 and 2000. (York Report at 4 and 10.) This review found that evidence supports that fluoridated water has a preventative effect on (reduces) tooth decay disease while increasing dental fluorosis. (*Id.* at xiv.) It found "little high quality research has been undertaken." (*Id.*) It found that "The research evidence is of insufficient quality to allow confident statements about other potential harms."

(vii) Description of the manufacturing processes, including the sources of all components.

The water will come from a well. The Fluoridation Products will be selected from the ANSI/NSF certified products. *See* subsection (iv) herein. The chemicals will be metered into flowing water in a manner to maintain the specified chemical concentration rates. The Sodium Fluoride will be injected using an up-draft fluoride saturator. The injection rate into the transmission line in the control house will be controlled using a 4 to 20 milliamperes signal from the main water meter so that finished fluoridation levels are close to 0.7 mg/L. Fluoride levels will be manually checked twice daily.

(viii) Proposed use or indications:

Fluoridated public drinking water is supplied to aid in the prevention and prophylactic treatment of dental caries disease. The proposed product will be used to prevent dental caries disease.

(ix) Description of all known modes of action, the sponsor's identification of the single mode of action that provides the most important therapeutic action of the product, and the basis for that determination:

Fluoride is believed to increase enamel resistance to acid solubility, making the teeth less susceptible to plaque acid attack, thereby producing its cariostatic effect. (60 FR 52483.) Fluoride benefits are topical. (60 FR 52473-510.) When children eat meals or snacks containing fermentable sugars, the plaque bacteria plus sugar creates acid which demineralizes the enamel creating lesions. Saliva washes the acid away between meals and snacks which promotes remineralization of the enamel. Topical fluoride added to the remineralizing incipient lesions increases the enamel crystals' resistance to dissolution by plaque acids. H. Limeback, *Comprehensive Preventive Dentistry* (UK; John Wiley & Sons, Ltd., 2012) ("Limeback") pages 13-15. The chemical process by which topical fluoride increases the enamel crystals' resistance

Att. 12

to dissolution is further described *Id.* at pages 252-56. For most of the last 60 years, the buildup of fluoride in the mineralized tooth tissues during tooth development was thought to render them more resistant to the effects of plaque acids. *Id.* More recently, however, there has been a paradigm shift in terms of our understanding of how fluoride works. *Id.* It is now well established that fluoride has a direct topical influence on the dynamic mineralization-remineralization process that occurs under the plaque biofilm that adheres to tooth enamel (crown portion of the tooth) as well as cementum and dentin (exposed surfaces of the root). *Id.* The idea that fluoride pills taken daily during tooth development, or the consumption of fluoridated water, will make teeth "stronger" and more resistant to decay has been largely abandoned in many countries. *Id.* Fluoride appears to provide its benefit when present in the oral cavity. *Id.* Its effectiveness depends on how frequently it is administered in the mouth, and the mechanism of fluoride's topical anti-caries effect will depend on the mode of application, its chemical formulation and, especially its concentration. *Id.*

Enamel is composed primarily (about 95%) of hydroxyapatite (HA) crystals in which are substituted a number of other ions including fluoride. *Id.* Fluoride substituting for the hydroxyl group fits extremely well and stabilizes the HA molecule forming fluoridated apatite. *Id.* If all of the hydroxyl ions are substituted, fluorapatite (FA) forms. *Id.* The fluoride ion is extremely electronegative and forms very strong hydrogen bonds with hydroxyl and acid phosphate groups in the HA crystal rendering the enamel surface more difficult to protonate. *Id.* Essentially, this makes the enamel more difficult to demineralize, and it also favors the remineralization process. *Id.* This is the primary chemical mechanism of fluoride's action to protect the tooth against acids produced by plaque metabolism. *Id.* In summary, the acidogenic plaque bacteria produce mainly lactic acid, which dissociates into lactate and protons. *Id.* The lower pH encourages apatite crystal dissolution into component ions. *Id.* When the acid is neutralized, the fluoride ion enters the remineralizing crystal and replaces the hydroxyl group resulting in a crystal that is enriched in fluorapatite (FA). *Id.*

The carious lesion begins with demineralization of the enamel surface components that are not fluoride-rich. *Id.* Only soluble components (carbonate and magnesium rich) are likely to be removed. *Id.* A fluoride-rich surface area inhibits the exit of dissolved calcium and phosphate resulting in a buildup of calcium-phosphate ions. *Id.* This together with the high fluoride tends to favor reprecipitation preserving the apparent integrity of the surface layer. *Id.* This feature of an incipient lesion is extremely important. *Id.* Without an intact surface layer, plaque would get trapped in the early cavitations and undoubtedly speed the progress of the carious lesion. *Id.* The removal of destabilizing carbonate and magnesium and accumulation of fluoride by the lesion renders it less acid soluble allowing potential remineralization that prevents further decay and heals the lesion. *Id.* Fluoride encourages remineralization for two reasons. *Id.* First, the solubility products of fluoride-enriched minerals are lowered. *Id.* Secondly, as fluoride is incorporated into recrystallizing apatite crystals, hydroxyl groups are released, which neutralize some of the protons produced by the bacteria (the hydroxyl groups 'mop up' some protons and combine with them to form water). *Id.* The removal of protons increases the pH, and this will further drive the solubility reaction toward the precipitation of apatite in the demineralization and remineralization cycles. *Id.* Fluoride, topically applied, appears to be accumulated in plaque and is then slowly released into the underlying enamel at low pH. *Id.* Overall, the data, points convincingly to the fact that fluoride's action is primarily at the level of the incipient lesion, and plaque may actually aid in providing the fluoride. Water fluoridation as a source of topical fluoride is further described *Id.* at pages 266-68. Because of the disadvantages of ingestion of fluoride, some question whether the likely very small benefit of water fluoridation is warranted. *Id.*

(x) Schedule and duration of use:

A#.18

Fluoridated public drinking water is consumed in the same manner that non-fluoridated public drinking water is consumed without limitation as to time of use.

(xi) Dose and route of administration of drug or biologic:

There is no management proposed regarding the consumption of fluoridated public drinking water. The fluoridated water is typically consumed by drinking several times each day. There are reports of absorption of fluoride through the skin from fluoridated water used for bathing. The U.S. Department of Health and Human Services ("HHS"), Centers for Disease Control and Prevention ("CDC") issued "Recommendation for Using Fluoride to Prevent and Control Dental Caries in the United States" in MMWR, August 17, 2001, Vol. 50, No. RR-14, which at page 9 states that average adults get 1-3 mg fluoride per day in fluoridated areas and up to 1 mg fluoride per day in nonfluoridated areas which suggests an adult average fluoride dose range from fluoridated water of 1-2 mg per day. Said page 9 states that children who live in optimally fluoridated areas average 0.05 mg/kg/day which is twice the average for children who live in nonfluoridated areas which suggests a child average fluoride dose from fluoridated water of 0.025 mg/kg/day. Based on an average range of water intake, said page 9 suggests that a child's range of fluoride doses from fluoridated water would be 0.01 to 0.05 mg/kg/day. Limeback at page 277 states that "Patients who consume large quantities of water or who have renal problems should avoid fluoridated water altogether." Up to 1% of people are allergic to fluoride and should avoid fluoridated water.

(xii) Description of related products, including the regulatory status of those related products:

Fluoridated public drinking water is commonly manufactured by various water purveyors including water districts, utility districts, and municipalities. As long as fluoride ion levels stay below 2.0 ppm in public drinking water these additives are not regulated by EPA. In 1952, the FDA adopted a regulation stating that "water supplies containing fluorine, within the limitations recommended by the Public Health Service, [will not be] actionable under the Federal Food, Drug, and Cosmetic Act." (Former CFR 3.27 (1952); 17 FR 6732.) This regulation was recodified to former 21 CFR 250.203 in 1975. (40 FR 13996.) It was published, as amended, in 1995. (21 Parts 200 to 299, Revised as of April 1, 1995, a Special Edition of the Federal Register.) In 1996, the FDA determined that its 1952 regulation was obsolete or no longer necessary and the regulation was revoked. (61 FR 29476.) The revocation of 21 CFR 250.203 occurred after the EPA gave notice in 1988 announcing the "Termination of the Federal Drinking Water Additive Program" effective April 7, 1990. (53 FR 25586-89.) This 1988 EPA Notice gave FDA and the public Notice that EPA would no longer comply with Agreement Terms III(A)(1) and III(A)(3) in the 1979 MOU. (*Id.*; *See* subsection (2)(iv) above for the 1979 MOU – these Agreement Terms are marked with a "D" on Attachment A-4 hereto.) Subsection IV of the 1979 MOU (marked with an "E" on Attachment A-4 hereto) required FDA to consent to the EPA changes to the Terms of Agreement (by adopting and publishing a revised MOU – *see* Attachment A-3 hereto just above the beginning of the Memorandum of Understanding) or otherwise, thirty days after the 1988 EPA Notice, the 1979 MOU would terminate. There was no revised MOU so the 1979 MOU did terminate in 1988.

Today, most states require public water additives to comply with ANSI/NSF Standard 60. This is acceptable, except for special additives that meet the definition of a drug in 21 USC 321(g)(1)(B) because these special additives are "intended for use in the prevention of disease in man." Such special additives are clearly under the regulatory oversight of CDER in the FDA because these additives are drugs. The Safe Drinking Water Act ("SDWA") in 42 USC 300g-1(b)(11)

Att. 14

specifically prevents regulation by the SDWA of "any substance for preventative health care purposes unrelated to contamination." Therefore such substances can only be regulated by the FDCA as drugs. *See* Attachment A-8 and A-9 hereto. Fluoridation Chemicals are such substances. If Fluoridation Chemicals are drugs then we believe that when these chemicals are compounded with our water, the resulting fluoridated drinking water would also be a drug. We would make fluoridated drinking water only if the FDA found it safe and effective in the prevention of dental caries disease and if all of our customers consented to fluoridation.

Fluorides are minerals. 21 USC 321ff ("Dietary Supplement Health and Education Act of 1994) states that minerals are foods except when they meet the definition of a drug. The Federal Supreme Court states that the definition of "drug" in 21 USC 321(g)(1)(B) is "as broad as its literal language indicates." (*United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 793-801, 89 S.Ct. 1410, 22 L.Ed.2d 726 (1969).) The National Sanitation Foundation ("NSF"), HHS, CDC and others all acknowledge that Fluoridation Chemicals are "intended for use in the prevention of disease in man." These Fluoridation Chemicals must be designated as drugs under the regulatory authority of CDER. They are prescription drugs because they do not meet the conditions in 21 CFR 310 et seq. in the Anticaries Drug Products for Over-the-Counter Human Use; Final Monograph. When these prescription drugs are compounded with public drinking water, the resulting fluoridated water is also a prescription drug because it does not meet the conditions in the Anticaries Final Monograph.

(xiii) Any other relevant information:

None.

(3) The sponsor's recommendation as to which agency component should have primary jurisdiction:

FDA CDER should have jurisdiction over Kailin Public Water System water fluoridation and its fluoridated public drinking water if it is fluoridated using Sodium Fluoride with intent to prevent dental caries disease.

Respectfully submitted,

Gerald Steel, PE, Attorney at Law

Attachments: A-1 to A-9

AH. 15

February 2008

NSF Fact Sheet on Fluoridation Chemicals

Introduction

This fact sheet provides information on the fluoride containing water treatment additives that NSF has tested and certified to NSF/ANSI Standard 60: Drinking Water Chemicals - Health Effects. According to the latest Association of State Drinking Water Administrators Survey on State Adoption of NSF/ANSI Standards 60 and 61, 45 states require that chemicals used in treating potable water must meet Standard 60 requirements. If you have questions on your state's requirements, or how the NSF/ANSI Standard 60 certified products are used in your state, you should contact your state's Drinking Water Administrator.

Water fluoridation is the practice of adjusting the fluoride content of drinking water. Fluoride is added to water for the public health benefit of preventing and reducing tooth decay and improving the health of the community. The U.S. Centers for Disease Control and Prevention is a reliable source of information on this important public health intervention. For more information please visit www.cdc.gov/fluoridation/.

NSF certifies three basic products in the fluoridation category:

1. Fluorosilicic Acid (aka Fluosilicic Acid or Hydrofluosilicic Acid).
2. Sodium Fluorosilicate (aka Sodium Silicofluoride).
3. Sodium Fluoride.

NSF Standard 60

Products used for drinking water treatment are evaluated to the criteria specified in NSF/ANSI Standard 60. This standard was developed by an NSF-led consortium, including the American Water Works Association (AWWA), the American Water Works Association Research Foundation (AWWARF), the Association of State Drinking Water Administrators (ASDWA), and the Conference of State Health and Environmental Managers (COSHEM). This group developed NSF/ANSI Standard 60, at the request of the US EPA Office of Water, in 1988. The NSF Joint Committee on Drinking Water Additives continues to review and maintain the standard annually. This committee consists of representatives from the original stakeholder groups as well as other regulatory, water utility and product manufacturer representatives.

Standard 60 was developed to establish minimum requirements for the control of potential adverse human health effects from products added directly to water during its treatment, storage and distribution. The standard requires a full formulation disclosure of each chemical ingredient in a product. It also requires a toxicology review to determine that the product is safe at its maximum use level and to evaluate potential contaminants in the product. The standard requires testing of the treatment chemical products, typically by dosing these in water at 10 times the maximum use level, so that trace levels of contaminants can be detected. A toxicology evaluation of test results is required to determine if any contaminant concentrations have the potential to cause adverse human health effects. The standard sets criteria for the establishment of single product allowable concentrations (SPAC) of each respective contaminant. For contaminants regulated by the U.S. EPA, this SPAC has a default level not to exceed ten-percent of the regulatory level to provide protection for the consumer in the unlikely event of multiple sources of the contaminant, unless a lower or higher number of sources can be specifically identified.

NSF Certification

NSF also developed a testing and certification program for these products, so that individual U.S. states and waterworks facilities would have a mechanism to determine which products were appropriate for use. The certification program requires annual unannounced inspections of production and distribution facilities to ensure that the products are properly formulated, packaged, and transported with safe guards against potential contamination. NSF also requires annual testing and toxicological evaluation of each NSF Certified product. NSF Certified products have the NSF Mark, the maximum use level, lot number or date code and production location on the product packaging or documentation shipped with the product.

The use of this standard and the associated certification program have yielded benefits in ensuring that drinking water additives meet the health objectives that provide the basis for public health protection. NSF maintains listings of companies that manufacture and distribute treatment products at www.nsf.org. These listings are updated daily and list the products at their allowable maximum use levels. In recognition of the important safeguards that NSF Standard 60 provides to public drinking water supplies, 45 U.S. States and 10 Canadian Provinces and Territories require drinking water treatment chemicals to comply with the requirements of the standard.

Treatment products that are used for fluoridation are addressed in Section 7 of NSF/ANSI Standard 60. The products are allowed to be used up to concentrations that result in a maximum use level of 1.2 mg/L fluoride ion in water. The NSF standard requires that the treatment products added to drinking water, as well as any impurities in the products, are supported by toxicological evaluation. The following text explains the rationale for the allowable levels established in the standard for 1) fluoride, 2) silicate, and 3) other potential contaminants that may be associated with fluoridation chemicals.

Fluoride

NSF/ANSI Standard 60 requires, when available, that the US EPA regulated maximum contaminant level (MCL) be used to determine the acceptable level for a contaminant. The EPA MCL for fluoride ion in water is 4 mg/L. The NSF Standard 60 single product allowable concentration (SPAC) for fluoride ion in drinking water from NSF Certified treatment products is 1.2 mg/L, or less than one-third of the EPA's MCL. Based on this the allowable maximum use level (MUL) for the NSF Certified fluoridation products are:

1. Fluorosilicic Acid: 6 mg/L.
2. Sodium Fluorosilicate: 2 mg/L.
3. Sodium Fluoride: 2.3 mg/L.

Silicate

There is no EPA MCL for silicate in drinking water. When an MCL does not exist for a contaminant, NSF/ANSI Standard 60 provides criteria to conduct a toxicological risk assessment of the contaminant and the development of a SPAC. NSF has established a SPAC for silicate at 16 mg/L. A fluorosilicate product, applied at its maximum use level, results in silicate drinking water levels that are substantially below the 16 mg/L SPAC established by NSF. For example, a sodium fluorosilicate product dosed at a concentration into drinking water that would provide the maximum concentration of fluoride allowed (1.2mg/L) would only contribute 0.8 mg/L of silicate – or 5 percent of the SPAC allowed by NSF 60.

A-2

Att. 17

Federal facilities. Prior to making a final recommendation to the Administrator, U.S. EPA, the Regional Administrator, Region V, is providing opportunity for public comment on the State of Wisconsin request. Any interested person may comment upon the State request by writing to the U.S. EPA, Region V Office, 230 South Dearborn Street, Chicago, Illinois 60604, Attention: Permit Branch. Such comments will be made available to the public for inspection and copying. All comments or objections received by August 22, 1979, will be considered by U.S. EPA before taking final action on the Wisconsin request for authority to issue permits to Federal facilities.

The State's request, related documents, and all comments received are on file and may be inspected and copied (@ 20 cents/page) at the U.S. EPA, Region V Office, in Chicago.

Copies of this notice are available upon request from the Enforcement Division of U.S. EPA, Region V, by contacting Dorothy A. Price, Public Notice Clerk (312-353-2105), at the above address.

Dated: July 13, 1979.

John McGuire,

Regional Administrator.

[FR Doc. 79-22072 Filed 7-19-79; 8:45 am]

BILLING CODE 6560-01-M

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

ENVIRONMENTAL PROTECTION AGENCY

[FRL 1275-4]

Drinking Water Technical Assistance; Implementation Plan for Control of Direct and Indirect Additives to Drinking Water and Memorandum of Understanding Between the Environmental Protection Agency and the Food and Drug Administration

AGENCY: Environmental Protection Agency and Food Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) have executed a memorandum of understanding (MOU) with regard to the control of direct and indirect additives to and substances in drinking water. The purpose of the MOU is to avoid the possibility of overlapping jurisdiction between EPA and FDA with respect to control of drinking water additives. The agreement became effective on June 22, 1979.

ADDRESS: Submit comments to: Victor J. Kimm, Deputy Assistant Administrator for Drinking Water, Environmental Protection Agency (WH-550), Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT: David W. Schnare, Ph.D., Office of Drinking Water (WH-550), Environmental Protection Agency, Washington, D.C. 20460, (202) 755-5843; or Gary Dykstra, Enforcement Policy Staff (HFC-22), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, (301) 443-3470.

SUPPLEMENTARY INFORMATION: In the spirit of interagency cooperation and to avoid the possibility of overlapping jurisdiction over additives and other substances in drinking water, FDA and EPA have entered into a memorandum of understanding to avoid duplicative and inconsistent regulation. In brief, the memorandum provides that EPA will have primary responsibility over direct and indirect additives and other substances in drinking water under the Safe Drinking Water Act, the Toxic Substances Control Act, and the Federal Insecticide, Fungicide and Rodenticide Act. FDA will have responsibility for water, and substances in water, used in food and for food processing and for bottled water under the Federal Food, Drug and Cosmetic Act.

Pursuant to the notice published in the Federal Register of October 3, 1974, (39 FR 35697) stating that future memoranda of understanding, and agreements between FDA and others would be published in the Federal Register, the following memorandum of understanding is issued:

Memorandum of Understanding Between the Environmental Protection Agency and the Food and Drug Administration

I. Purpose

This Memorandum of Understanding establishes an agreement between the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) with regard to the control of direct and indirect additives to and substances in drinking water.

EPA and FDA agree:

(1) That contamination of drinking water from the use and application of direct and indirect additives and other substances poses a potential public health problem;

(2) That the scope of the additives problem in terms of the health significance of these contaminants in drinking water is not fully known;

(3) That the possibility of overlapping jurisdiction between EPA and FDA with respect to control of drinking water additives has been the subject of Congressional as well as public concern;

(4) That the authority to control the use and application of direct and indirect additives to and substances in drinking water should be vested in a single regulatory agency to avoid duplicative and inconsistent regulation;

(5) That EPA has been mandated by Congress under the Safe Drinking Water Act (SDWA), as amended, to assure that the public is provided with safe drinking water;

(6) That EPA has been mandated by Congress under the Toxic Substances Control Act (TSCA) to protect against unreasonable risks to health and the environment from toxic substances by requiring, *inter alia*, testing and necessary restrictions on the use, manufacture, processing, distribution, and disposal of chemical substances and mixtures;

(7) That EPA has been mandated by Congress under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to assure, *inter alia*, that when used properly, pesticides will perform their intended function without causing unreasonable adverse effects on the environment; and,

(8) That FDA has been mandated by Congress under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended, to protect the public from, *inter alia*, the adulteration of food by food additives and poisonous and deleterious substances.

It is the intent of the parties that:

(1) EPA will have responsibility for direct and indirect additives to and other substances in drinking water under the SDWA, TSCA, and FIFRA; and,

(2) FDA will have responsibility for water, and substances in water, used in food and for food processing and responsibility for bottled drinking water under the FFDCA.

II. Background

(A) *FDA Legal Authority.* "Food" means articles used for food or drink for man or other animals and components of such articles. (FFDCA § 201(f)). Under Section 402, *inter alia*, a food may not contain any added poisonous or deleterious substance that may render it injurious to health, or be prepared, packed or handled under unsanitary conditions. Tolerances may be set, under Section 406, limiting the quantity of any substance which is required for the production of food or cannot be avoided in food. FDA has the authority under Section 409 to issue food additive regulations approving, with or without conditions, or denying the use of a "food additive." That term is defined in Section 201(s) to include any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, if such substance is not generally recognized as safe.

In the past, FDA has considered drinking water to be a food under Section 201(f). However, both parties have determined that the passage of the SDWA in 1974 implicitly repealed FDA's authority under the FFDCA over water used for drinking water purposes. Under the express provisions of Section 410

A-3

AH. 18

of the FFDCA. FDA retains authority over bottled drinking water. Furthermore, all water used in food remains a food and subject to the provisions of the FFDCA. Water used for food processing is subject to applicable provisions of FFDCA. Moreover, all substances in water used in food are added substances subject to the provisions of the FFDCA, but no substances added to a public drinking water system before the water enters a food processing establishment will be considered a food additive.

(B). *EPA Legal Authority:* The SDWA grants EPA the authority to control contaminants in drinking water which may have any adverse effect on the public health, through the establishment of maximum contaminant levels (MCLs) or treatment techniques, under Section 1412, which are applicable to owners and operators of public water systems. The expressed intent of the Act was to give EPA exclusive control over the safety of public water supplies. Public water systems may also be required by regulation to conduct monitoring for unregulated contaminants under Section 1445 and to issue public notification of such levels under Section 1414(c).

EPA's direct authority to control additives to drinking water apart from the existence of maximum contaminant levels or treatment techniques is limited to its emergency powers under Section 1431. However, Section 1442(b) of the act authorizes EPA to "collect and make available information pertaining to research, investigations, and demonstrations with respect to providing a dependably safe supply of drinking water together with appropriate recommendations therewith."

TSCA gives EPA authority to regulate chemical substances, mixtures and under some circumstances, articles containing such substances or mixtures. Section 4 permits EPA to require testing of a chemical substance or mixture based on possible unreasonable risk of injury to health or the environment, or on significant or substantial human or environmental exposure while Section 8 enables EPA to require submission of data showing substantial risk of injury to health of the environment, existing health and safety studies, and other data. For new chemical substances, and significant new uses of existing chemical substances, Section 5 requires manufacturers to provide EPA with premanufacturing notice. Under Section 6 the manufacture, processing, distribution, use, and disposal of a chemical substance or mixture determined to be harmful may be restricted or banned. Although Section 3(2)(B) of TSCA excludes from the definition of "chemical substance" food and food additives as defined under FFDCA, the implicit repeal by the SDWA of FDA's authority over drinking water enables EPA to regulate direct and indirect additives to drinking water as chemical substances and mixtures under TSCA.

The FIFRA requires EPA to set restrictions on the use of pesticides to assure that when used properly, they will not cause unreasonable adverse effects on the environment. EPA may require, *inter alia*, labeling which specifies how, when, and where a pesticide may be legally used. In addition, EPA has, under Section 409 of the FFDCA, required FIFRA registrants at times to obtain a food additive tolerance before using a pesticide in or around a drinking water source. Such tolerances establish further restrictions on the use of a pesticide which are enforceable against the water supplier as well as the registrant of the pesticide.

III. Terms of Agreement

(A) EPA's responsibilities are as follows:

(1) To establish appropriate regulations, and to take appropriate measures; under the SDWA and/or TSCA, and FIFRA, to control direct additives to drinking water (which encompass any substances purposely added to the water), and indirect additives (which encompass any substances which might leach from paints, coatings or other materials as an incidental result of drinking water contact), and other substances.

(2) To establish appropriate regulations under the SDWA to limit the concentrations of pesticides in drinking water; the limitations on concentrations and types of pesticides in water are presently set by EPA through tolerances under Section 409 of the FFDCA.

(3) To continue to provide technical assistance in the form of informal advisory opinions on drinking water additives under Section 1442(b) of the SDWA.

(4) To conduct and require research and monitoring and the submission of data relative to the problem of direct and indirect additives in drinking water in order to accumulate data concerning the health risks posed by the presence of these contaminants in drinking water.

(B). FDA's responsibilities are as follows:

(1) To take appropriate regulatory action under the authority of the FFDCA to control bottled drinking water and water, and substances in water, used in food and for food processing.

(2) To provide assistance to EPA to facilitate the transition of responsibilities, including:

(a) To review existing FDA approvals in order to identify their applicability to additives in drinking water.

(b) To provide a mutually agreed upon level of assistance in conducting literature searches related to toxicological decision making.

(c) To provide a senior toxicologist to help EPA devise new procedures and protocols to be used in formulating advice on direct and indirect additives to drinking water.

IV. Duration of Agreement

This Memorandum of Understanding shall continue in effect unless modified by mutual consent of both parties or terminated by either party upon thirty (30) days advance written notice to the other.

This Memorandum of Understanding will become effective on the date of the last signature.

Dated: June 13, 1979.

Douglas M. Costle,

Administrator, Environmental Protection Agency.

Dated: June 22, 1979.

Donald Kennedy,

Administrator, Food and Drug Administration.

Implementation Plan

EPA is concerned that direct and indirect additives may be adding harmful trace chemical contaminants into our Nation's drinking water during treatment, storage and distribution. Direct additives include such chemicals as chlorine, lime, alum, and congulant aides, which are added at the water treatment plant. Although these chemicals themselves may be harmless, they may contain small amounts of harmful chemicals if their quality is not controlled. Indirect additives include those contaminants which enter drinking water through leaching, from pipes, tanks and other equipment, and their associated paints and coatings. This notice is being published in the Federal Register to solicit public comment on EPA's implementation plan to assess and control direct and indirect additives in drinking water.

Legal Authorities

EPA and the Food and Drug Administration (FDA) signed a Memorandum of Understanding which recognizes that regulatory control over direct and indirect additives in drinking water is placed in EPA. The two agencies agreed that the Safe Drinking Water Act's passage in 1974 implicitly repealed FDA's jurisdiction over drinking water as a 'food' under the Federal Food, Drug and Cosmetic Act (FFDCA). Under the agreement, EPA now retains exclusive jurisdiction over drinking water served by public water supplies, including any additives in such water. FDA retains jurisdiction over bottled drinking water under Section 410 of the FFDCA and over water (and substances in water) used in food or food processing once it enters the food processing establishment.

In implementing its new responsibilities, EPA may utilize a variety of statutory authorities, as appropriate. The authorities are identified in Appendix A.

Under the Safe Drinking Water Act, EPA has authority to set and enforce maximum contaminant levels and treatment techniques in drinking water for ubiquitous contaminants, to conduct research, to offer technical assistance to States and to protect against imminent

A-4

AH.19

hazards should such situations arise. Under the Toxic Substances Control Act, EPA has authority to review all new chemicals proposed for use related to drinking water, to mandate toxicological testing of existing and new chemicals where there is evidence that such materials may pose an unreasonable risk to health and the environment as well as authority to limit some or all uses of harmful chemicals. Pesticide use is regulated by EPA under the Federal Insecticide, Fungicide and Rodenticide Act. Thus, EPA believes it has adequate authority to deal with additives to drinking water where they may pose a problem.

Past Actions

For more than ten years, the Public Health Service and other organizations which have become part of EPA have provided advisory opinions on the toxicological safety of a variety of additives to drinking water. These historical informal opinions reflect a variety of information provided by manufacturers and reflect changing toxicological concerns over the years. As such, they will require detailed review over the next few years.

General Approach

EPA intends to begin its responsibility over additives to drinking water with a series of analytical studies to determine the composition and significance of the health risks posed by contaminants related to direct and indirect additives to drinking water. A first step in this process will be monitoring studies of the contaminants actually getting into drinking water from generic categories of additives like bulk chemicals, paints and coatings, pipes and equipment.

In the initial six to twelve months, EPA will develop interim administrative procedures, testing protocols, and decision criteria for future toxicological advisories to the States. These will be distributed for public comment once they are developed. All existing opinions will remain in effect until a general review of past opinions can be undertaken using the new procedures. During this development phase, no new opinions will be rendered unless a proposed product can be shown to be virtually identical to a product for which an opinion has already been rendered, on the basis of chemical formulation and production process. New products or new uses of existing products which are proposed for use in drinking water will be subject to the pre-manufacture notice procedures of TSCA.

A more detailed outline of the steps to be taken by EPA follows.

1. *Problem Definition.*—EPA will contract for *in situ* monitoring to determine use patterns and the contribution of trace contaminants to drinking water from:

a. bulk chemicals.

b. generic classes of paints and coatings.

c. pipes and equipment.

d. coagulant aids.

EPA has already contracted with the National Academy of Sciences to develop a CODEX system of quality control standards for chemicals (direct additives) used in the treatment of drinking water. This effort will take about three years to complete. When finished, the CODEX system, modeled on the existing FDA-inspired CODEX system for chemicals used in processing food, will be largely self-enforcing.

For the indirect additives listed in items b and c above, considerable effort will be expended to identify the trace contaminants involved before the related health risks can be fully evaluated and appropriate recommendations for future use can be assessed.

2. *Review of Past Advisories.*—The same data base derived from *in situ* monitoring will serve as a basis for a structured reassessment of past toxicological advisories which will be conducted by generic classes of use e.g., paints, coagulant aides, etc. Past opinions will be reviewed to insure conformance with and satisfaction of new test protocols and decision criteria that will be developed.

3. *Future Toxicological Advisories.*—Once initial procedures, test protocols and decision criteria are developed, EPA will resume offering toxicological opinions to the States.

General Policy

In assessing additives to drinking water, EPA will be guided by a policy of reducing public health risks to the degree it is feasible to do so. In such determinations, EPA will evaluate the risks and benefits associated with the materials of concern and their substitutes. Economic impacts of agency actions will also be analyzed.

Notwithstanding these procedures, EPA would use its authorities to protect against any direct or indirect additive to drinking water when data and information indicate that the use of any additive may pose an undue risk to public health.

Implementation

To fulfill this program, resources from the Office of Drinking Water, the Office of Research and Development, and the Office of Toxic Substances will be used. In addition, EPA looks forward to the cooperation of FDA and other Federal regulatory bodies. EPA intends to involve interested industry groups, independent testing groups, State regulatory bodies, interested members of the public, and industry standards groups, in a continued effort to ensure the safety of the Nation's drinking water.

Finally, EPA may recommend specialized legislative authority to regulate additives to drinking water should a situation arise for which legal authorities prove inadequate.

Lead responsibility for this new Federal initiative will be in EPA's Office of Drinking Water. Public comments on any or all aspects of the proposed program are requested, and should be directed to the address given in the opening sections of this notice.

Dated: July 13, 1979.

Thomas C. Jorling,

Assistant Administrator for Water and Waste Management.

Appendix A

Safe Drinking Water Act

Section 1412—establishment of national primary drinking water regulations applicable to public water systems to control contaminants in drinking water which may have any adverse effect on human health. This may include maximum contaminant levels, treatment techniques, monitoring requirements, and quality control and testing procedures.

Section 1431—use of emergency powers where a contaminant which is present in water, or is likely to enter a public water system, may present an imminent and substantial endangerment to the health of persons.

Section 1445—establishment of monitoring and reporting requirements applicable to public water systems.

Section 1450—authority to prescribe such regulations as are necessary or appropriate to carry out the Administrator's functions under the Act.

Toxic Substances Control Act

Section 4—testing of chemical substances and mixtures.

Section 5—pre-manufacture notice required for new chemicals or significant new uses.

Section 6—regulation of hazardous chemical substances and mixtures which pose an unreasonable risk of injury to health or the environment, including restrictions on manufacture, processing, distribution, and use.

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A-5

AH. 20

Section 7—imminent hazards authority including seizure and other relief through civil court action.

Section 8—reporting and retention of information as required by the Administrator, including health and safety studies and notice to the Administrator of substantial risks.

Section 10—research and development. Development of systems for storing, retrieving and disseminating data.

Section 11—inspections and subpenas and other enforcement and general administration provisions therein.

Federal Insecticide, Fungicide and Rodenticide Act

Section 3—registration of pesticides, including imposition of restrictions and labeling requirements.

Section 6—suspension and cancellation procedures.

[FR Doc. 79-22222 Filed 7-19-79; 8:45 am]

BILLING CODE 6560-01-M

BILLING CODE 4110-03-M

FEDERAL COMMUNICATIONS COMMISSION

[Report No. A-1a]

FM Broadcasting Applications Accepted for Filing and Notification of Cut-Off Date; Erratum

Released: July 12, 1979.

The FM Application listed below was inadvertently included on the acceptance/cut-off notice, Report No. A-1, BC Mimeo No. 18676, released on June 25, 1979.

BPH-790108AE [New]; Gresson, Pennsylvania. Sherlock-Hart Broadcasting, Inc.

Req.: 94.9 MHz, Channel #234A. ERP: 0.600 kW, HAAT: 800 feet.

Accordingly, the application is removed from the acceptance/cutoff list and the August 8, 1979, cutoff date is deleted.

Federal Communications Commission.

William J. Tricarico,

Secretary.

[FR Doc. 79-22422 Filed 7-19-79; 8:45 am]

BILLING CODE 6712-01-M

FEDERAL LABOR RELATIONS AUTHORITY

Official Time of Employees Involved in Negotiating Collective Bargaining Agreements

AGENCY: Federal Labor Relations Authority.

ACTION: Notice Relating to Official Time.

SUMMARY: This notice principally relates to the interpretation of section 7131 of the Federal Service Labor-Management Relations Statute (92 Stat. 1214) on the questions of whether employees who are on official time under this section while representing an exclusive representative in the negotiation of a collective bargaining agreement are entitled to payments from agencies for their travel and per diem expenses, and whether the official time provisions of section 7131(a) of the Statute encompass all negotiations between an exclusive representative and an agency, regardless of whether such negotiations pertain to the negotiation or renegotiation of a basic collective bargaining agreement. The notice further invites interested persons to address the impact, if any, of section 7135(a)(1) of the Statute (92 Stat. 1215) on such interpretation and to submit written comments concerning these matters.

DATE: Written comments must be submitted by the close of business on August 24, 1979, to be considered.

ADDRESS: Send written comments to the Federal Labor Relations Authority, 1900 E Street, NW., Washington, D.C. 20424.

FOR FURTHER INFORMATION CONTACT: Harold D. Kessler, Deputy Executive Director, 1900 E Street, NW., Washington, D.C. 20424, (202) 632-3920.

SUPPLEMENTARY INFORMATION: The Federal Labor Relations Authority was established by Reorganization Plan No. 2 of 1978, effective January 1, 1979 (43 FR 36037). Since January 11, 1979, the Authority has conducted its operations under the Federal Service Labor-Management Relations Statute (92 Stat. 1191).

Upon receipt of requests and consideration thereof the Authority has determined, in accordance with 5 CFR 2410.3(a) (1978) and sections 7105 and 7135(b) of the Statute (92 Stat. 1198, 1215), that an interpretation is warranted concerning section 7131 of the Statute (92 Stat. 1214). Interested persons are invited to express their views in writing on this matter, as more fully explained in the Authority's notice set forth below:

To Heads of Agencies, Presidents of Labor Organizations and Other Interested Persons

The Authority has received a request from the American Federation of Government Employees (AFGE) for a statement of policy and guidance concerning whether employees representing an exclusive representative in the negotiation of a collective bargaining agreement are entitled to payments from agencies for their travel and per diem expenses under the official time provisions of section 7131 of the Federal Service Labor-Management Relations Statute (92 Stat. 1214). Additionally, the National Federation of Federal Employees (NFFE) has requested a major policy statement as to the application of the official time provisions of section 7131(a) of the Statute (92 Stat. 1214) to all negotiations between an exclusive representative and an agency, regardless of whether such negotiations pertain to the negotiation or renegotiation of a basic collective bargaining agreement. AFGE has raised a similar issue in its request.

The Authority hereby determines, in conformity with 5 CFR 2410.3(a) (1978) and section 7135(b) of the Statute (92 Stat. 1215), as well as section 7105 of the Statute (92 Stat. 1198), that an interpretation of the Statute is warranted on the following:

(1) Whether employees who are on official time under section 7131 of the Statute while representing an exclusive representative in the negotiation of a collective bargaining agreement are entitled to payments from agencies for their travel and per diem expenses.

(2) Whether the official time provisions of section 7131(a) of the Statute encompass all negotiations between an exclusive representative and an agency, regardless of whether such negotiations pertain to the negotiation or renegotiation of a basic collective bargaining agreement.

Before issuing an interpretation on the above, the Authority, pursuant to 5 CFR 2410.3 (1978) and section 7135(b) of the Statute (92 Stat. 1215), solicits your views in writing. You are further invited to address the impact, if any, of section 7135(a)(1) of the Statute (92 Stat. 1215) on the above matters and to submit your views as to whether oral argument should be granted. To receive consideration, such views must be submitted to the Authority by the close of business on August 24, 1979.

Issued, Washington, D.C., July 13, 1979.

Federal Labor Relations Authority.

Ronald W. Haughton,

Chairman.

Henry B. Frazier III,

Member.

[FR Doc. 79-22443 Filed 7-19-79; 8:45 am]

BILLING CODE 6325-01-M

A-6

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SOLVAY FLUORIDES
A SUBSIDIARY OF SOLVAY CHEMICALS, INC.

CERTIFICATE OF ANALYSIS

Batch: 0907112

625583

Information Provided to:	Shipped To:
UNIVAR USA PO Box 34325 SEATTLE, WA 98124	UNIVAR USA 3950 NORTH WEST YEON PORTLAND OR 97210 UNITED STATES
Contact: BEN *Fax:* 425-889-3702	

Order Information on Shipment of: SODIUM FLUORIDE COARSE - 50 LB BAG	Sold-To: UNIVAR USA		
Customer Purchase Order No.: PO 679906	Material Code: 625583	Dry Short Tons:	Delivery / BOL No.: 80976244
Shipping Date: 10/23/2009	Shipping Vehicle No.: SLT EXPRESS WAY	Net Weight: 40,000 LB	Number and Type of Package: 800 BAG

Comment(s):

CUSTOMER SPECIFICATION ANALYSIS	RESULT	UNIT	MIN	MAX
Assay	98.750	%	97.000	
Insolubles	0.28	%		0.60
Water	0.24	%		0.50
Heavy Metals (as Pb)	0.0120	%		
Screen Analysis, US	% Retained			
20 US Screen	1.8	%		2.0
100 US Screen	65.1	%	50.0	
-325 US Screen	2.1	%		5.0

SUPPLIER:	APPROVED BY:
Solvay Fluorides, L.L.C. 3333 Richmond Ave 77098 HOUSTON Phone: 800-443-2785	Patricia Hill Quality Manager Solvay Chemicals, Inc. 3333 Richmond Ave. Houston, TX 77098 Phone 713-525-6510

A-7
AH-22

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
GENERAL COUNSEL

February 14, 2013

Gerald Steel, PE
7303 Young Road NW
Olympia, WA 98502

Dear Mr. Steel:

This is in response to your letter of December 28, 2012 to EPA Administrator Lisa Jackson in which you asked several questions about the status of an MOU between EPA and the Federal Drug Administration (FDA) published in 1979. I am replying on behalf of her.

Your first question is whether, from the viewpoint of EPA, the purpose of a 1979 Memorandum of Understanding (MOU) between EPA and the Federal Drug Administration (FDA) was "to take away from FDA, and give to EPA, responsibility for regulating public drinking water additives intended for preventative health care purposes and unrelated to contamination of public drinking water?" Your second question is whether, if that was the purpose of the 1979 MOU, the MOU was terminated through a subsequent Federal Register notice.

The answer to your first question is no, so there is no need to address your second question. The purpose of the MOU was not to shift any responsibilities between the Agencies. Rather, it was to help facilitate effective coordination of our respective legal authorities. Under the Safe Drinking Water Act (SDWA), EPA is the lead federal agency with responsibility to regulate the safety of public water supplies. EPA does not have responsibility for substances added to water solely for preventative health care purposes, such as fluoride, other than to limit the addition of such substances to protect public health or to prevent such substances from interfering with the effectiveness of any required treatment techniques. SDWA Section 1412(b)(11); see also A Legislative History of the Safe Drinking Water Act, Committee Print, 97th Cong, 2d Session (February 1982) at 547. The Department of Health and Human Services (HHS), acting through the FDA, remains responsible for regulating the addition of drugs to water supplies for health care purposes.

The 1979 MOU was intended to address contamination of drinking water supplies as a result of direct or indirect additives to drinking water, not to address the addition of substances solely for preventative health purposes. 44 Fed. Reg. 42775 (July 20, 1979) ("EPA and FDA agree: (1) that *contamination* of drinking water from the use and application of direct and indirect additives and other substances poses a potential public health problem...")(emphasis added). It was intended to avoid potentially duplicative regulation of "food", which FDA had, in the past, considered to include drinking water. 44 Fed. Reg. 42775 (July 20, 1979). The MOU did not address drugs or other substances added to water for health care purposes.

A-8
Att. 23

I hope that this has adequately answered your inquiry. Please do not hesitate to contact Carrie Wehling of my staff (202-564-5492) if you have further questions about this.

Sincerely,

Steven M. Neugeboren
Associate General Counsel
Water Law Office

A-9
Att. 24

Gerald Steel PE
Attorney at Law
7303 Young Rd. NW
Olympia WA 98502
360.867.1166 Phone

January 13, 2015

Product Jurisdiction Officer
Food and Drug Administration
10903 New Hampshire Ave
Bldg. 32, rm. 5129
Silver Spring, MD 20993-0002

RE: 21 CFR 3.6 § 3.7. Request for Designation – Libera Bottled Fluoridated Water with Sodium Fluoride and "drug claim" on label

Dear Product Jurisdiction Officer:

I hereby submit an original and two copies of this Request for Designation under the authority of 21 CFR § 3.7(a)(2).

Information provided pursuant to 21 CFR § 3.7 (c):

(1) The identity of the sponsor, including company name and address, establishment registration number, company contact person and telephone number.

The sponsor is: Mike Libera
316 Power Plant Rd.
Port Angeles, WA 98363

There is no establishment registration number at this time.
The contact persons and telephone numbers are:
Mike Libera, Sole Proprietor 360.457.5662
Gerald Steel, Attorney 360.867.1166

(2) Description of the product:

(i) Classification, name of the product and all component products, if applicable:

The product is bottled Sequim WA municipal water, fluoridated by the sponsor, Mike Libera, and intended for use in the prevention of dental caries (tooth decay) disease in man. It will be composed of one gallon bottles (and later bottles of other sizes) of unfluoridated municipal water from the City of Sequim WA with an added fluoridation product certified to meet ANSI/NSF Standard 60 and used with the intent of preventing tooth decay disease: Sodium Fluoride with a maximum addition of 2.3 mg/L. *See* Attachments A-1 and A-2 hereto from the NSF Fact Sheet on certified Fluoridation Chemicals. The City of Sequim public drinking water system is registered with the Washington State Department of Health as PWS ID# 77620Y. The Libera bottling plant will be on industrial zoned land, location to be determined, in the City of Sequim. The plant will have a minimum size connection to the City of Sequim municipal water system of 1". To install the fluoridation system described below in subsection (2)(vii), a 1" line will be

Att. 25

routed from the connection to a small fluoridation vented-room where fluoridation will occur. Fluoridated water will then be transmitted to a bottling and labeling machine that meets health department standards. We are submitting this request for designation prior to submitting an application for premarket review. The product labels will include the drug claim that "This drinking water is intended for use in the prevention of tooth decay disease.

(ii) Common, generic, or usual name of the product and all component products:

The common name is fluoridated drinking water or artificially fluoridated drinking water. The common name of the fluoridation chemical are listed in subsection (2)(i) above.

(iii) Proprietary name of the product:

There is no proprietary name of the product at this time.

(iv) Identification of any component of the product that already has received premarket approval, is marketed as not being subject to premarket approval, or has received an investigational exemption, the identity of the sponsors, and the status of any discussions or agreements between sponsors regarding the use of this product as a component of a new combination product.

Public drinking water without added Fluoridation Chemicals is properly marketed as not being subject to premarket approval by the FDA. To the best of our knowledge, all Fluoridation Chemicals are marketed without premarket approval by the FDA even though these products are intended for use in the prevention of disease in man. (*See* Attachment A-1, para. 2, hereto.) To the best of our knowledge, all Fluoridation Chemicals are certified to meet ANSI/NSF Standard 60. (*See* Attachments A-1 and A-2 hereto.) Names and addresses for the manufacturers of Fluoridation Chemicals that are certified to meet ANSI/NSF Standard 60 are found at http://www.nsf.org/Certified/PwsChemicals/Listings.asp?ProductFunction=Fluoridation& and http://www.wqa.org/goldseal/6.html There are 24 pages of additional listings by Underwriters Laboratories, Inc. that can be provided upon request. To the best of our knowledge, none of the Fluoridation Chemicals have received an investigational exemption. To the best of our knowledge, there are no other sponsors who have submitted or currently intend to submit an application to FDA for premarket review for bottled fluoridated water with a drug claim. We have not yet held discussions with any of the manufacturers of Fluoridation Chemicals. If we must limit this request to a specific manufacturer of Sodium Fluoride, we limit it to the product described in Attachment A-7 hereto. However, we would prefer to not commit to any specific manufacturer at this time in order to minimize product costs.

In 1979, the EPA and FDA entered a Memorandum of Understanding ("MOU 225-79-2001"). This 1979 MOU is published in 44 FR 42775-78 (Vol. 44, No. 141 of the Federal Register (July 20, 1979) pages 42775-78 – provided in Attachments A-3 to A-6 hereto). Section II.A of this MOU cites the FDA legal authorities being negotiated in this MOU. (Section marked with "B" on Attachments A-3 and A-4 hereto.) The only FDA authorities being negotiated were "food" and "food additive" responsibilities. FDA drug responsibilities were not being negotiated and are not covered by this MOU. This is confirmed by a recent letter from the EPA. Attachment A-8 and A-9 hereto.

(v) Chemical, physical, or biological composition:

The chemical composition is described in subsection (2)(i) above. Attachment A-7 hereto is a

Att. 26

typical Certificate of Analysis for Sodium Fluoride. Any selected Sodium Fluoride will be certified to comply with ANSI/NSF Standard 60.

(vi) Status and brief reports of the results of developmental work, including animal testing:

Fluoridated water is being consumed today by a majority of people in the United States. Artificially fluoridated public water was first introduced in 1944. M. McDonagh et al., *A Systematic Review of Public Water Fluoridation* (NHS Centre of Reviews and Dissemination – University of York - 2000) (the "York Report") reviewed 3246 studies on public fluoridated water published between 1939 and 2000. (York Report at 4 and 10.) This review found that evidence supports that fluoridated water has a preventative effect on (reduces) tooth decay disease while increasing dental fluorosis. (*Id.* at xiv.) It found "little high quality research has been undertaken." (*Id.*) It found that "The research evidence is of insufficient quality to allow confident statements about other potential harms."

(vii) Description of the manufacturing processes, including the sources of all components.

The water will come from the City of Sequim WA municipal water system. The Fluoridation Chemicals would be selected from the ANSI/NSF certified products. *See* subsection (iv) herein. The chemicals would be metered into flowing water in a manner to maintain the specified chemical concentration rates. The Sodium Fluoride would be injected using an up-draft fluoride saturator. The injection rate into the supply line in the control room would be controlled using a 4 to 20 milliamperes signal from the main water meter so that finished fluoridation levels are close to 0.7 mg/L. Fluoride levels would be manually checked twice daily. Bottles will be 128 oz. Natural HDPE Beverage Containers with orange ratchet cap from Freund Container & Supply (or equal).

(viii) Proposed use or indications:

This fluoridated drinking water is supplied to aid in the prevention and prophylactic treatment of dental caries disease. The proposed product would be used to prevent dental caries disease.

(ix) Description of all known modes of action, the sponsor's identification of the single mode of action that provides the most important therapeutic action of the product, and the basis for that determination:

Fluoride is believed to increase enamel resistance to acid solubility, making the teeth less susceptible to plaque acid attack, thereby producing its cariostatic effect. (60 FR 52483.) Fluoride benefits are topical. (60 FR 52473-510.) When children eat meals or snacks containing fermentable sugars, the plaque bacteria plus sugar creates acid which demineralizes the enamel creating lesions. Saliva washes the acid away between meals and snacks which promotes remineralization of the enamel. Topical fluoride added to the remineralizing incipient lesions increases the enamel crystals' resistance to dissolution by plaque acids. H. Limeback, *Comprehensive Preventive Dentistry* (UK; John Wiley & Sons, Ltd., 2012) ("Limeback") pages 13-15. The chemical process by which topical fluoride increases the enamel crystals' resistance to dissolution is further described *Id.* at pages 252-56. For most of the last 60 years, the buildup of fluoride in the mineralized tooth tissues during tooth development was thought to render them more resistant to the effects of plaque acids. *Id.* More recently, however, there has been a paradigm shift in terms of our understanding of how fluoride works. *Id.* It is now well

Att. 17

established that fluoride has a direct topical influence on the dynamic mineralization-remineralization process that occurs under the plaque biofilm that adheres to tooth enamel (crown portion of the tooth) as well as cementum and dentin (exposed surfaces of the root). *Id.* The idea that fluoride pills taken daily during tooth development, or the consumption of fluoridated water, will make teeth "stronger" and more resistant to decay has been largely abandoned in many countries. *Id.* Fluoride appears to provide its benefit when present in the oral cavity. *Id.* Its effectiveness depends on how frequently it is administered in the mouth, and the mechanism of fluoride's topical anti-caries effect will depend on the mode of application, its chemical formulation and, especially its concentration. *Id.*

Enamel is composed primarily (about 95%) of hydroxyapatite (HA) crystals in which are substituted a number of other ions including fluoride. *Id.* Fluoride substituting for the hydroxyl group fits extremely well and stabilizes the HA molecule forming fluoridated apatite. *Id.* If all of the hydroxyl ions are substituted, fluorapatite (FA) forms. *Id.* The fluoride ion is extremely electronegative and forms very strong hydrogen bonds with hydroxyl and acid phosphate groups in the HA crystal rendering the enamel surface more difficult to protonate. *Id.* Essentially, this makes the enamel more difficult to demineralize, and it also favors the remineralization process. *Id.* This is the primary chemical mechanism of fluoride's action to protect the tooth against acids produced by plaque metabolism. *Id.* In summary, the acidogenic plaque bacteria produce mainly lactic acid, which dissociates into lactate and protons. *Id.* The lower pH encourages apatite crystal dissolution into component ions. *Id.* When the acid is neutralized, the fluoride ion enters the remineralizing crystal and replaces the hydroxyl group resulting in a crystal that is enriched in fluorapatite (FA). *Id.*

The carious lesion begins with demineralization of the enamel surface components that are not fluoride-rich. *Id.* Only soluble components (carbonate and magnesium rich) are likely to be removed. *Id.* A fluoride-rich surface area inhibits the exit of dissolved calcium and phosphate resulting in a buildup of calcium-phosphate ions. *Id.* This together with the high fluoride tends to favor reprecipitation preserving the apparent integrity of the surface layer. *Id.* This feature of an incipient lesion is extremely important. *Id.* Without an intact surface layer, plaque would get trapped in the early cavitations and undoubtedly speed the progress of the carious lesion. *Id.* The removal of destabilizing carbonate and magnesium and accumulation of fluoride by the lesion renders it less acid soluble allowing potential remineralization that prevents further decay and heals the lesion. *Id.* Fluoride encourages remineralization for two reasons. *Id.* First, the solubility products of fluoride-enriched minerals are lowered. *Id.* Secondly, as fluoride is incorporated into recrystallizing apatite crystals, hydroxyl groups are released, which neutralize some of the protons produced by the bacteria (the hydroxyl groups 'mop up' some protons and combine with them to form water). *Id.* The removal of protons increases the pH, and this will further drive the solubility reaction toward the precipitation of apatite in the demineralization and remineralization cycles. *Id.* Fluoride, topically applied, appears to be accumulated in plaque and is then slowly released into the underlying enamel at low pH. *Id.* Overall, the data, points convincingly to the fact that fluoride's action is primarily at the level of the incipient lesion, and plaque may actually aid in providing the fluoride. Water fluoridation as a source of topical fluoride is further described *Id.* at pages 266-68. Because of the disadvantages of ingestion of fluoride, some question whether the likely very small benefit of water fluoridation is warranted. *Id.*

(x) Schedule and duration of use:

Fluoridated bottled drinking water is intended to be consumed in the same manner as non-fluoridated public drinking water is consumed without limitation as to time of use.

(xi) Dose and route of administration of drug or biologic:

Aff. 2B

There is no management proposed regarding the consumption of fluoridated bottled drinking water. The fluoridated bottled water would typically be consumed by drinking several times each day. The U.S. Department of Health and Human Services ("HHS"), Centers for Disease Control and Prevention ("CDC") issued "Recommendation for Using Fluoride to Prevent and Control Dental Caries in the United States" in MMWR, August 17, 2001, Vol. 50, No. RR-14, which at page 9 states that average adults get 1-3 mg fluoride per day when drinking fluoridated water and up to 1 mg fluoride per day when not drinking fluoridated water which suggests an adult average fluoride dose range from fluoridated water of 1-2 mg per day. Said page 9 states that children who drink optimally fluoridated water average 0.05 mg/kg/day which is twice the average for children who do not drink fluoridated water which suggests a child average fluoride dose from fluoridated water of 0.025 mg/kg/day. Based on an average range of water intake, said page 9 suggests that a child's range of fluoride doses from fluoridated water would be 0.01 to 0.05 mg/kg/day. Limeback at page 277 states that "Patients who consume large quantities of water or who have renal problems should avoid fluoridated water altogether." Up to 1% of people are allergic to fluoride and should avoid fluoridated water.

(xii) Description of related products, including the regulatory status of those related products:

Fluoridated public drinking water is commonly manufactured by various water purveyors including water districts, utility districts, and municipalities. As long as fluoride ion levels stay below 2.0 ppm in public drinking water these additives are not regulated by EPA. In 1952, the FDA adopted a regulation stating that "water supplies containing fluorine, within the limitations recommended by the Public Health Service, [will not be] actionable under the Federal Food, Drug, and Cosmetic Act." (Former CFR 3.27 (1952); 17 FR 6732.) This regulation was recodified to former 21 CFR 250.203 in 1975. (40 FR 13996.) It was published, as amended, in 1995. (21 Parts 200 to 299, Revised as of April 1, 1995, a Special Edition of the Federal Register.) In 1996, the FDA determined that its 1952 regulation was obsolete or no longer necessary and the regulation was revoked. (61 FR 29476.) The revocation of 21 CFR 250.203 occurred after the EPA gave notice in 1988 announcing the "Termination of the Federal Drinking Water Additive Program" effective April 7, 1990. (53 FR 25586-89.) This 1988 EPA Notice gave FDA and the public Notice that EPA would no longer comply with Agreement Terms III(A)(1) and III(A)(3) in the 1979 MOU. (*Id.*; *See* subsection (2)(iv) above for the 1979 MOU – these Agreement Terms are marked with a "D" on Attachment A-4 hereto.) Subsection IV of the 1979 MOU (marked with an "E" on Attachment A-4 hereto) required FDA to consent to the EPA changes to the Terms of Agreement (by adopting and publishing a revised MOU – *see* Attachment A-3 hereto just above the beginning of the Memorandum of Understanding) or otherwise, thirty days after the 1988 EPA Notice, the 1979 MOU would terminate. There was no revised MOU so the 1979 MOU did terminate in 1988.

Today, most states require public water additives to comply with ANSI/NSF Standard 60. This is acceptable, except for special additives that meet the definition of a drug in 21 USC 321(g)(1)(B) because these special additives are "intended for use in the prevention of disease in man." Such special additives are clearly under the regulatory oversight of CDER in the FDA because these additives are drugs. The Safe Drinking Water Act ("SDWA") in 42 USC 300g-1(b)(11) specifically prevents regulation by the SDWA of "any substance for preventative health care purposes unrelated to contamination." Therefore such substances can only be regulated by the FDCA as drugs. *See* Attachment A-8 and A-9 hereto. Fluoridation Chemicals are such substances. If Fluoridation Chemicals are drugs then we believe that when these chemicals are compounded with municipal water, the resulting fluoridated drinking water would also be a drug.

Aff. 29

We would make fluoridated bottled drinking water only if the FDA found it safe and effective in the prevention of dental caries disease.

Fluorides are minerals. 21 USC 321ff ("Dietary Supplement Health and Education Act of 1994) states that minerals are foods except when they meet the definition of a drug. The Federal Supreme Court states that the definition of "drug" in 21 USC 321(g)(1)(B) is "as broad as its literal language indicates." (*United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 793-801, 89 S.Ct. 1410, 22 L.Ed.2d 726 (1969).) The National Sanitation Foundation ("NSF"), HHS, CDC and others all acknowledge that Fluoridation Chemicals are "intended for use in the prevention of disease in man." These Fluoridation Chemicals must be designated as drugs under the regulatory authority of CDER. When these drugs are compounded with public drinking water, the resulting fluoridated bottled water is also a drug if a drug claim is being made in the labeling.

The FDA has ruled that fluoridated bottled water is not a drug if it includes only a health claim. http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm073602.htm The FDA, on request, has ruled that bottled water may make a health claim if it meets the standards of identity and quality set forth in 21 CFR 165.110, contains greater than 0.6 and up to 1.0 mg/L *total* fluoride, and meets all general requirements for health claims (21 CFR 101.14) with the exception of minimum nutrient contribution (21 CFR 101.14 (e)(6)). The claim language is: "Drinking fluoridated water may reduce the risk of [dental caries or tooth decay]." In addition, this health claim is not intended for use on bottled water products specifically marketed for use by infants. Libera fluoridated bottled water will not make a health claim but will rather make a drug claim.

(xiii) Any other relevant information:

None.

(3) The sponsor's recommendation as to which agency component should have primary jurisdiction:

FDA CDER should have jurisdiction over Libera Bottled Fluoridated Water with Sodium Fluoride when the bottles are labeled with a drug claim.

Respectfully submitted,

Gerald Steel, PE, Attorney at Law

Attachments: A-1 to A-9

February 2008

NSF Fact Sheet on Fluoridation Chemicals

Introduction

This fact sheet provides information on the fluoride containing water treatment additives that NSF has tested and certified to NSF/ANSI Standard 60: Drinking Water Chemicals - Health Effects. According to the latest Association of State Drinking Water Administrators Survey on State Adoption of NSF/ANSI Standards 60 and 61, 45 states require that chemicals used in treating potable water must meet Standard 60 requirements. If you have questions on your state's requirements, or how the NSF/ANSI Standard 60 certified products are used in your state, you should contact your state's Drinking Water Administrator.

Water fluoridation is the practice of adjusting the fluoride content of drinking water. Fluoride is added to water for the public health benefit of preventing and reducing tooth decay and improving the health of the community. The U.S. Centers for Disease Control and Prevention is a reliable source of information on this important public health intervention. For more information please visit www.cdc.gov/fluoridation/.

NSF certifies three basic products in the fluoridation category:

1. Fluorosilicic Acid (aka Fluosilicic Acid or Hydrofluosilicic Acid).
2. Sodium Fluorosilicate (aka Sodium Silicofluoride).
3. Sodium Fluoride.

NSF Standard 60

Products used for drinking water treatment are evaluated to the criteria specified in NSF/ANSI Standard 60. This standard was developed by an NSF-led consortium, including the American Water Works Association (AWWA), the American Water Works Association Research Foundation (AWWARF), the Association of State Drinking Water Administrators (ASDWA), and the Conference of State Health and Environmental Managers (COSHEM). This group developed NSF/ANSI Standard 60, at the request of the US EPA Office of Water, in 1988. The NSF Joint Committee on Drinking Water Additives continues to review and maintain the standard annually. This committee consists of representatives from the original stakeholder groups as well as other regulatory, water utility and product manufacturer representatives.

Standard 60 was developed to establish minimum requirements for the control of potential adverse human health effects from products added directly to water during its treatment, storage and distribution. The standard requires a full formulation disclosure of each chemical ingredient in a product. It also requires a toxicology review to determine that the product is safe at its maximum use level and to evaluate potential contaminants in the product. The standard requires testing of the treatment chemical products, typically by dosing these in water at 10 times the maximum use level, so that trace levels of contaminants can be detected. A toxicology evaluation of test results is required to determine if any contaminant concentrations have the potential to cause adverse human health effects. The standard sets criteria for the establishment of single product allowable concentrations (SPAC) of each respective contaminant. For contaminants regulated by the U.S. EPA, this SPAC has a default level not to exceed ten-percent of the regulatory level to provide protection for the consumer in the unlikely event of multiple sources of the contaminant, unless a lower or higher number of sources can be specifically identified.

A-1

Att 31

NSF Certification

NSF also developed a testing and certification program for these products, so that individual U.S. states and waterworks facilities would have a mechanism to determine which products were appropriate for use. The certification program requires annual unannounced inspections of production and distribution facilities to ensure that the products are properly formulated, packaged, and transported with safe guards against potential contamination. NSF also requires annual testing and toxicological evaluation of each NSF Certified product. NSF Certified products have the NSF Mark, the maximum use level, lot number or date code and production location on the product packaging or documentation shipped with the product.

The use of this standard and the associated certification program have yielded benefits in ensuring that drinking water additives meet the health objectives that provide the basis for public health protection. NSF maintains listings of companies that manufacture and distribute treatment products at www.nsf.org. These listings are updated daily and list the products at their allowable maximum use levels. In recognition of the important safeguards that NSF Standard 60 provides to public drinking water supplies, 45 U.S. States and 10 Canadian Provinces and Territories require drinking water treatment chemicals to comply with the requirements of the standard.

Treatment products that are used for fluoridation are addressed in Section 7 of NSF/ANSI Standard 60. The products are allowed to be used up to concentrations that result in a maximum use level of 1.2 mg/L fluoride ion in water. The NSF standard requires that the treatment products added to drinking water, as well as any impurities in the products, are supported by toxicological evaluation. The following text explains the rationale for the allowable levels established in the standard for 1) fluoride, 2) silicate, and 3) other potential contaminants that may be associated with fluoridation chemicals.

Fluoride

NSF/ANSI Standard 60 requires, when available, that the US EPA regulated maximum contaminant level (MCL) be used to determine the acceptable level for a contaminant. The EPA MCL for fluoride ion in water is 4 mg/L. The NSF Standard 60 single product allowable concentration (SPAC) for fluoride ion in drinking water from NSF Certified treatment products is 1.2 mg/L, or less than one-third of the EPA's MCL. Based on this the allowable maximum use level (MUL) for the NSF Certified fluoridation products are:

1. Fluorosilicic Acid: 6 mg/L.
2. Sodium Fluorosilicate: 2 mg/L.
3. Sodium Fluoride: 2.3 mg/L.

Silicate

There is no EPA MCL for silicate in drinking water. When an MCL does not exist for a contaminant, NSF/ANSI Standard 60 provides criteria to conduct a toxicological risk assessment of the contaminant and the development of a SPAC. NSF has established a SPAC for silicate at 16 mg/L. A fluorosilicate product, applied at its maximum use level, results in silicate drinking water levels that are substantially below the 16 mg/L SPAC established by NSF. For example, a sodium fluorosilicate product dosed at a concentration into drinking water that would provide the maximum concentration of fluoride allowed (1.2mg/L) would only contribute 0.8 mg/L of silicate – or 5 percent of the SPAC allowed by NSF 60.

A-2

Att. 32

Federal facilities. Prior to making a final recommendation to the Administrator, U.S. EPA, the Regional Administrator, Region V, is providing opportunity for public comment on the State of Wisconsin request. Any interested person may comment upon the State request by writing to the U.S. EPA, Region V Office, 230 South Dearborn Street, Chicago, Illinois 60604, Attention: Permit Branch. Such comments will be made available to the public for inspection and copying. All comments or objections received by August 22, 1979, will be considered by U.S. EPA before taking final action on the Wisconsin request for authority to issue permits to Federal facilities.

The State's request, related documents, and any comments received are on file and may be inspected and copied (@ 20 cents/page) at the U.S. EPA, Region V Office, in Chicago.

Copies of this notice are available upon request from the Enforcement Division of U.S. EPA, Region V, by contacting Dorothy Aldrich, Public Notice Clerk (312-353-2108), at the above address.

Dated: July 13, 1979.

John McGuire,

Regional Administrator.

[FR Doc. 79-21972 Filed 7-19-79; 8:45 am]

BILLING CODE 6560-01-M

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

ENVIRONMENTAL PROTECTION AGENCY

[FRL 1275-4]

Drinking Water Technical Assistance; Implementation Plan for Control of Direct and Indirect Additives to Drinking Water and Memorandum of Understanding Between the Environmental Protection Agency and the Food and Drug Administration

AGENCY: Environmental Protection Agency and Food Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) have executed a memorandum of understanding (MOU) with regard to the control of direct and indirect additives to and substances in drinking water. The purpose of the MOU is to avoid the possibility of overlapping jurisdiction between EPA and FDA with respect to control of drinking water additives. The agreement became effective on June 22, 1979.

ADDRESS: Submit comments to: Victor J. Kimm, Deputy Assistant Administrator for Drinking Water, Environmental Protection Agency (WH-550), Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT: David W. Schnare, Ph.D., Office of Drinking Water (WH-550), Environmental Protection Agency, Washington, D.C. 20460, (202) 755-5343; or Gary Dykstra, Enforcement Policy Staff (HFC-22), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, (301) 443-3470.

SUPPLEMENTARY INFORMATION: In the spirit of interagency cooperation and to avoid the possibility of overlapping jurisdiction over additives and other substances in drinking water, FDA and EPA have entered into a memorandum of understanding to avoid duplicative and inconsistent regulation. In brief, the memorandum provides that EPA will have primary responsibility over direct and indirect additives and other substances in drinking water under the Safe Drinking Water Act, the Toxic Substances Control Act, and the Federal Insecticide, Fungicide and Rodenticide Act. FDA will have responsibility for water, and substances in water, used in food and for food processing and for bottled water under the Federal Food, Drug and Cosmetic Act.

Pursuant to the notice published in the Federal Register of October 3, 1974, (39 FR 35837) stating that future memoranda of understanding, and agreements between FDA and others would be published in the Federal Register, the following memorandum of understanding is issued:

Memorandum of Understanding Between the Environmental Protection Agency and the Food and Drug Administration

I. Purpose

This Memorandum of Understanding establishes an agreement between the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) with regard to the control of direct and indirect additives to and substances in drinking water.

EPA and FDA agree:

(1) That contamination of drinking water from the use and application of direct and indirect additives and other substances poses a potential public health problem;

(2) That the scope of the additives problem in terms of the health significance of these contaminants in drinking water is not fully known;

(3) That the possibility of overlapping jurisdiction between EPA and FDA with respect to control of drinking water additives has been the subject of Congressional as well as public concern;

(4) That the authority to control the use and application of direct and indirect additives to and substances in drinking water should be vested in a single regulatory agency to avoid duplicative and inconsistent regulation;

(5) That EPA has been mandated by Congress under the Safe Drinking Water Act (SDWA), as amended, to assure that the public is provided with safe drinking water;

(6) That EPA has been mandated by Congress under the Toxic Substances Control Act (TSCA) to protect against unreasonable risks to health and the environment from toxic substances by requiring, *inter alia*, testing and necessary restrictions on the use, manufacture, processing, distribution, and disposal of chemical substances and mixtures;

(7) That EPA has been mandated by Congress under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to assure, *inter alia*, that when used properly, pesticides will perform their intended function without causing unreasonable adverse effects on the environment; and,

(8) That FDA has been mandated by Congress under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended, to protect the public from, *inter alia*, the adulteration of food by food additives and poisonous and deleterious substances.

It is the intent of the parties that:

(1) EPA will have responsibility for direct and indirect additives to and other substances in drinking water under the SDWA, TSCA, and FIFRA; and,

(2) FDA will have responsibility for water, and substances in water, used in food and for food processing and responsibility for bottled drinking water under the FFDCA.

II. Background

(A) *FDA Legal Authority.* "Food" means articles used for food or drink for man or other animals and components of such articles. (FFDCA § 201(f)). Under Section 402 *inter alia*, a food may not contain any added poisonous or deleterious substance that may render it injurious to health, or be prepared, packed or handled under unsanitary conditions. Tolerances may be set, under Section 408, limiting the quantity of any substance which is required for the production of food or cannot be avoided in food. FDA has the authority under Section 409 to issue food additive regulations approving, with or without conditions, or denying the use of a "food additive." That term is defined in Section 201(s) to include any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, if such substance is not generally recognized as safe.

In the past, FDA has considered drinking water to be a food under Section 201(f). However, both parties have determined that the passage of the SDWA in 1974 implicitly expanded EPA's authority under the FFDCA over water used for drinking water purposes. Under the express provisions of Section 410

A-3
AH.33

of the FFDCA. FDA retains authority over bottled drinking water. Furthermore, all water used in food remains a food and subject to the provisions of the FFDCA. Water used for food processing is subject to applicable provisions of FFDCA. Moreover, all substances in water used in food are food additive substances subject to the provisions of the FFDCA, but no substances added to a public drinking water system before the water enters a food processing establishment will be considered a food additive.

(B). *EPA Legal Authority:* The SDWA grants EPA the authority to control contaminants in drinking water which may have any adverse effect on the public health, through the establishment of maximum contaminant levels (MCLs) or treatment techniques, under Section 1412, which are applicable to owners and operators of public water systems. The expressed intent of the Act was to give EPA exclusive control over the safety of public water supplies. Public water systems may also be required by regulation to conduct monitoring for unregulated contaminants under Section 1445 and to issue public notification of such levels under Section 1414(c).

EPA's direct authority to control additives to drinking water apart from the existence of maximum contaminant levels or treatment techniques is limited to its emergency powers under Section 1431. However, Section 1442(b) of the act authorizes EPA to "collect and make available information pertaining to research, investigations, and demonstrations with respect to providing a dependably safe supply of drinking water together with appropriate recommendations therewith."

TSCA gives EPA authority to regulate chemical substances, mixtures and under some circumstances, articles containing such substances or mixtures. Section 4 permits EPA to require testing of a chemical substance or mixture based on possible unreasonable risk of injury to health or the environment, or on significant or substantial human or environmental exposure while Section 8 enables EPA to require submission of data showing substantial risk of injury to health or the environment, existing health and safety studies, and other data. For new chemical substances, and significant new uses of existing chemical substances, Section 5 requires manufacturers to provide EPA with premanufacturing notice. Under Section 6 the manufacture, processing, distribution, use, and disposal of a chemical substance or mixture determined to be harmful may be restricted or banned. Although Section 3(2)(B) of TSCA excludes from the definition of "chemical substance" food and food additives as defined under FFDCA, the implicit repeal by the SDWA of FDA's authority over drinking water enables EPA to regulate direct and indirect additives to drinking water as chemical substances and mixtures under TSCA.

The FIFRA requires EPA to set restrictions on the use of pesticides to assure that when used properly, they will not cause unreasonable adverse effects on the environment. EPA may require, *inter alia*, labeling which specifies how, when, and where a pesticide may be legally used. In addition, EPA has, under Section 409 of the FFDCA, required FIFRA registrants at times to obtain a food additive tolerance before using a pesticide in or around a drinking water source. Such tolerances establish further restrictions on the use of a pesticide which are enforceable against the water supplier as well as the registrant of the pesticide.

III. Terms of Agreement

(A) EPA's responsibilities are as follows:

(1) To establish appropriate regulations, and to take appropriate measures; under the SDWA and/or TSCA, and FIFRA, to control direct additives to drinking water (which encompass any substances purposely added to the water), and indirect additives (which encompass any substances which might leach from paints, coatings or other materials as an incidental result of drinking water contact), and other substances.

(2) To establish appropriate regulations under the SDWA to limit the concentrations of pesticides in drinking water; the limitations on concentrations and types of pesticides in water are presently set by EPA through tolerances under Section 409 of the FFDCA.

(3) To continue to provide technical assistance in the form of informal advisory opinions on drinking water additives under Section 1442(b) of the SDWA.

(4) To conduct and require research and monitoring and the submission of data relative to the problem of direct and indirect additives in drinking water in order to accumulate data concerning the health risks posed by the presence of these contaminants in drinking water.

(B). FDA's responsibilities are as follows:

(1) To take appropriate regulatory action, under the authority of the FFDCA to control bottled drinking water and water, and substances in water, used in food and for food processing.

(2) To provide assistance to EPA to facilitate the transition of responsibilities, including:

(a) To review existing FDA approvals in order to identify their applicability to additives in drinking water.

(b) To provide a mutually agreed upon level of assistance in conducting literature searches related to toxicological decision making.

(c) To provide a senior toxicologist to help EPA devise new procedures and protocols to be used in formulating advice on direct and indirect additives to drinking water.

IV. Duration of Agreement

This Memorandum of Understanding shall continue in effect unless modified by mutual consent of both parties or terminated by either party upon thirty (30) days advance written notice to the other.

This Memorandum of Understanding will become effective on the date of the last signature.

Dated: June 13, 1979.

Douglas M. Costle,

Administrator, Environmental Protection Agency.

Dated: June 22, 1979.

Donald Kennedy,

Administrator, Food and Drug Administration.

Implementation Plan

EPA is concerned that direct and indirect additives may be adding harmful trace chemical contaminants into our Nation's drinking water during treatment, storage and distribution. Direct additives include such chemicals as chlorine, lime, alum, and coagulant aides, which are added at the water treatment plant. Although these chemicals themselves may be harmless, they may contain small amounts of harmful chemicals if their quality is not controlled. Indirect additives include those contaminants which enter drinking water through leaching, from pipes, tanks and other equipment, and their associated paints and coatings. This notice is being published in the Federal Register to solicit public comment on EPA's implementation plan to assess and control direct and indirect additives in drinking water.

Legal Authorities

EPA and the Food and Drug Administration (FDA) signed a Memorandum of Understanding which recognizes that regulatory control over direct and indirect additives in drinking water is placed in EPA. The two agencies agreed that the Safe Drinking Water Act's passage in 1974 implicitly repealed FDA's jurisdiction over drinking water as a "food" under the Federal Food, Drug and Cosmetic Act (FFDCA). Under the agreement, EPA now retains exclusive jurisdiction over drinking water served by public water supplies, including any additives in such water. FDA retains jurisdiction over bottled drinking water under Section 410 of the FFDCA and over water (and substances in water) used in food or food processing once it enters the food processing establishment.

In implementing its new responsibilities, EPA may utilize a variety of statutory authorities, as appropriate. The authorities are identified in Appendix A.

Under the Safe Drinking Water Act, EPA has authority to set and enforce maximum contaminant levels and treatment techniques in drinking water for ubiquitous contaminants, to conduct research, to offer technical assistance to States and to protect against imminent

A-4

AH.34

hazards should such situations arise. Under the Toxic Substances Control Act, EPA has authority to review all new chemicals proposed for use related to drinking water, to mandate toxicological testing of existing and new chemicals where there is evidence that such materials may pose an unreasonable risk to health and the environment as well as authority to limit some or all uses of harmful chemicals. Pesticide use is regulated by EPA under the Federal Insecticide, Fungicide and Rodenticide Act. Thus, EPA believes it has adequate authority to deal with additives to drinking water where they may pose a problem.

Past Actions

For more than ten years, the Public Health Service and other organizations which have become part of EPA have provided advisory opinions on the toxicological safety of a variety of additives to drinking water. These historical informal opinions reflect a variety of information provided by manufacturers and reflect changing toxicological concerns over the years. As such, they will require detailed review over the next few years.

General Approach

EPA intends to begin its responsibility over additives to drinking water with a series of analytical studies to determine the composition and significance of the health risks posed by contaminants related to direct and indirect additives to drinking water. A first step in this process will be monitoring studies of the contaminants actually getting into drinking water from generic categories of additives like bulk chemicals, paints and coatings, pipes and equipment.

In the initial six to twelve months, EPA will develop interim administrative procedures, testing protocols, and decision criteria for future toxicological advisories to the States. These will be distributed for public comment once they are developed. All existing opinions will remain in effect until a general review of past opinions can be undertaken using the new procedures. During this development phase, no new opinions will be rendered unless a proposed product can be shown to be virtually identical to a product for which an opinion has already been rendered, on the basis of chemical formulation and production process. New products or new uses of existing products which are proposed for use in drinking water will be subject to the pre-manufacture notice procedures of TSCA.

A more detailed outline of the steps to be taken by EPA follows.

1. *Problem Definition.*—EPA will contract for *in situ* monitoring to determine use patterns and the contribution of trace contaminants to drinking water from:

a. bulk chemicals.

b. generic classes of paints and coatings.

c. pipes and equipment.

d. coagulant aids.

EPA has already contracted with the National Academy of Sciences to develop a CODEX system of quality control standards for chemicals (direct additives) used in the treatment of drinking water. This effort will take about three years to complete. When finished, the CODEX system, modeled on the existing FDA-inspired CODEX system for chemicals used in processing food, will be largely self-enforcing.

For the indirect additives listed in items b and c above, considerable effort will be expended to identify the trace contaminants involved before the related health risks can be fully evaluated and appropriate recommendations for future use can be assessed.

2. *Review of Past Advisories.*—The same data base derived from *in situ* monitoring will serve as a basis for a structured reassessment of past toxicological advisories which will be conducted by generic classes of use e.g. paints, coagulant aides, etc. Past opinions will be reviewed to insure conformance with and satisfaction of new test protocols and decision criteria that will be developed.

3. *Future Toxicological Advisories.*—Once initial procedures, test protocols and decision criteria are developed, EPA will resume offering toxicological opinions to the States.

General Policy

In assessing additives to drinking water, EPA will be guided by a policy of reducing public health risks to the degree it is feasible to do so. In such determinations, EPA will evaluate the risks and benefits associated with the materials of concern and their substitutes. Economic impacts of agency actions will also be analyzed.

Notwithstanding these procedures, EPA would use its authorities to protect against any direct or indirect additive to drinking water when data and information indicate that the use of any additive may pose an undue risk to public health.

Implementation

To fulfill this program, resources from the Office of Drinking Water, the Office of Research and Development, and the Office of Toxic Substances will be used. In addition, EPA looks forward to the cooperation of FDA and other Federal regulatory bodies. EPA intends to involve interested industry groups, independent testing groups, State regulatory bodies, interested members of the public, and industry standards groups, in a continued effort to ensure the safety of the Nation's drinking water.

Finally, EPA may recommend specialized legislative authority to regulate additives to drinking water should a situation arise for which legal authorities prove inadequate.

Lead responsibility for this new Federal initiative will be in EPA's Office of Drinking Water. Public comments on any or all aspects of the proposed program are requested, and should be directed to the address given in the opening sections of this notice.

Dated: July 13, 1979.

Thomas C. Jorling,

Assistant Administrator for Water and Waste Management.

Appendix A

Safe Drinking Water Act

Section 1412—establishment of national primary drinking water regulations applicable to public water systems to control contaminants in drinking water which may have any adverse effect on human health. This may include maximum contaminant levels, treatment techniques, monitoring requirements, and quality control and testing procedures.

Section 1431—use of emergency powers where a contaminant which is present in water, or is likely to enter a public water system, may present an imminent and substantial endangerment to the health of persons.

Section 1445—establishment of monitoring and reporting requirements applicable to public water systems.

Section 1450—authority to prescribe such regulations as are necessary or appropriate to carry out the Administrator's functions under the Act.

Toxic Substances Control Act

Section 4—testing of chemical substances and mixtures.

Section 5—pre-manufacture notice required for new chemicals or significant new uses.

Section 6—regulation of hazardous chemical substances and mixtures which pose an unreasonable risk of injury to health or the environment, including restrictions on manufacture, processing, distribution, and use.

A-5
Att. 35

Section 7—imminent hazards authority including seizure and other relief through civil court action.

Section 8—reporting and retention of information as required by the Administrator, including health and safety studies and notice to the Administrator of substantial risks.

Section 10—research and development, Development of systems for storing, retrieving and disseminating data.

Section 11—inspections and subpenas and other enforcement and general administration provisions therein.

Federal Insecticide, Fungicide and Rodenticide Act

Section 3—registration of pesticides, including imposition of restrictions and labeling requirements.

Section 6—suspension and cancellation procedures.

[FR Doc. 79-22322 Filed 7-19-79; 8:45 am]

BILLING CODE 6560-01-M

BILLING CODE 4110-03-M

FEDERAL COMMUNICATIONS COMMISSION

[Report No. A-1a]

FM Broadcasting Applications Accepted for Filing and Notification of Cut-off Date; Erratum

Released: July 12, 1979.

The FM Application listed below was inadvertently included on the acceptance/cut-off notice, Report No. A-1, BC Mimeo No. 28978, released on June 25, 1979:

BPH-790108AE (New); Gresson, Pennsylvania. Sherlock-Hart Broadcasting, Inc.

Req.: 94.3 MHz, Channel #232A. ERP: 0.800 kW, HAAT: 500 feet.

Accordingly, the application is removed from the acceptance/cutoff list and the August 8, 1979, cutoff date is delisted.

Federal Communications Commission.

William J. Tricarico,

Secretary.

[FR Doc. 79-22323 Filed 7-19-79; 8:45 am]

BILLING CODE 6712-01-M

FEDERAL LABOR RELATIONS AUTHORITY

Official Time of Employees Involved in Negotiating Collective Bargaining Agreements

AGENCY: Federal Labor Relations Authority.

ACTION: Notice Relating to Official Time.

SUMMARY: This notice principally relates to the interpretation of section 7131 of the Federal Service Labor-Management Relations Statute (92 Stat. 1214) on the questions of whether employees who are on official time under this section while representing an exclusive representative in the negotiation of a collective bargaining agreement are entitled to payments from agencies for their travel and per diem expenses, and whether the official time provisions of section 7131(a) of the Statute encompass all negotiations between an exclusive representative and an agency, regardless of whether such negotiations pertain to the negotiation or renegotiation of a basic collective bargaining agreement. The notice further invites interested persons to address the impact, if any, of section 7135(a)(1) of the Statute (92 Stat. 1215) on such interpretations and to submit written comments concerning these matters.

DATE: Written comments must be submitted by the close of business on August 24, 1979, to be considered.

ADDRESS: Send written comments to the Federal Labor Relations Authority, 1900 E Street, NW., Washington, D.C. 20424.

FOR FURTHER INFORMATION CONTACT: Harold D. Kessler, Deputy Executive Director, 1900 E Street, NW., Washington, D.C. 20424, (202) 632-6320.

SUPPLEMENTARY INFORMATION: The Federal Labor Relations Authority was established by Reorganization Plan No. 2 of 1978, effective January 1, 1979 (43 FR 36037). Since January 11, 1979, the Authority has continued its operations under the Federal Service Labor-Management Relations Statute (92 Stat. 1191).

Upon receipt of requests and consideration thereof, the Authority has determined, in accordance with 5 CFR 2412.3(a) (1979) and sections 7105 and 7135(b) of the Statute (92 Stat. 1198, 1215), that an interpretation is warranted concerning section 7131 of the Statute (92 Stat. 1214). Interested persons are invited to express their views in writing on this matter, as more fully explained in the Authority's notice set forth below:

To Heads of Agencies, Presidents of Labor Organizations and Other Interested Persons

The Authority has received a request from the American Federation of Government Employees (AFGE) for a statement of policy and guidance concerning whether employees representing an exclusive representative in the negotiation of a collective bargaining agreement are entitled to payments from agencies for their travel and per diem expenses under the official time provisions of section 7131 of the Federal Service Labor-Management Relations Statute (92 Stat. 1214). Additionally, the National Federation of Federal Employees (NFFE) has requested a similar policy statement as to the application of the official time provisions of section 7131(a) of the Statute (92 Stat. 1214) to all negotiations between an exclusive representative and an agency, regardless of whether such negotiations pertain to the negotiation or renegotiation of a basic collective bargaining agreement. AFGE has raised a similar issue in its request.

The Authority hereby determines, in conformity with 5 CFR 2412.3(a) (1979) and section 7105(a) of the Statute (92 Stat. 1215), as well as section 7105 of the Statute (92 Stat. 1198), that an interpretation of the Statute is warranted on the following:

(1) Whether employees who are on official time under section 7131 of the Statute while representing an exclusive representative in the negotiation of a collective bargaining agreement are entitled to payments from agencies for their travel and per diem expenses.

(2) Whether the official time provisions of section 7131(a) of the Statute encompass all negotiations between an exclusive representative and an agency, regardless of whether such negotiations pertain to the negotiation or renegotiation of a basic collective bargaining agreement.

Before issuing an interpretation on the above, the Authority, pursuant to 5 CFR 2412.3 (1979) and section 7135(b) of the Statute (92 Stat. 1215), solicits your views in writing. You are further invited to address the impact, if any, of section 7135(a)(1) of the Statute (92 Stat. 1215) on the above matters and to submit your views as to whether oral argument should be granted. To receive consideration, such views must be submitted to the Authority by the close of business on August 24, 1979.

Issued, Washington, D.C., July 13, 1979.

Federal Labor Relations Authority.

Ronald W. Haughton,

Chairman.

Henry B. Frazier III,

Member.

[FR Doc. 79-22440 Filed 7-19-79; 8:45 am]

BILLING CODE 6325-01-M

A-6

Att. 36

SOLVAY FLUORIDES
A SUBSIDIARY OF SOLVAY CHEMICALS, INC.

CERTIFICATE OF ANALYSIS
Batch: 0907112

625583

Information Provided to:

UNIVAR USA
PO BOX [redacted]
SEATTLE, WA 98124

Contact: BEN
Fax: 425-889-3702

Shipped To:

UNIVAR USA
[redacted] WEST YEON
PORTLAND, OR 97210
UNITED STATES

Order Information on Shipment of:	Sold-To:		
SODIUM FLUORIDE COARSE - 50 LB BAG	UNIVAR USA		
Customer Purchase Order No.:	**Material Code:**	**Dry Short Tons:**	**Delivery / BOL No.:**
PO 679906	625583		80976244
Shipping Date:	**Shipping Vehicle No.:**	**Net Weight:**	**Number and Type of Package:**
10/23/2009	SLT EXPRESS WAY	40,000 LB	800 BAG

Comment(s):

CUSTOMER SPECIFICATION ANALYSIS	RESULT	UNIT	MIN	MAX
Assay	98.750	%	97.000	
Insolubles	0.28	%		0.60
Water	0.24	%		0.50
Heavy Metals (as Pb)	0.0120	%		
Screen Analysis, US	% Retained			
20 US Screen	1.8	%		2.0
100 US Screen	65.1	%	50.0	
-325 US Screen	2.1	%		5.0

SUPPLIER:

Solvay Fluorides, L.L.C.
[redacted] Ave
[redacted]
Phone: 800-[redacted]-2785

APPROVED BY:

Patricia [redacted]
[redacted], Inc.
[redacted]
Houston, [redacted]
Phone 713-[redacted]

A-7

AH.37

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
GENERAL COUNSEL

February 14, 2013

Gerald Steel, PE
7303 Young Road NW
Olympia, WA 98502

Dear Mr. Steel:

This is in response to your letter of December 28, 2012 to EPA Administrator Lisa Jackson in which you asked several questions about the status of an MOU between EPA and the Federal Drug Administration (FDA) published in 1979. I am replying on behalf of her.

Your first question is whether, from the viewpoint of EPA, the purpose of a 1979 Memorandum of Understanding (MOU) between EPA and the Federal Drug Administration (FDA) was "to take away from FDA, and give to EPA, responsibility for regulating public drinking water additives intended for preventative health care purposes and unrelated to contamination of public drinking water?" Your second question is whether, if that was the purpose of the 1979 MOU, the MOU was terminated through a subsequent Federal Register notice.

The answer to your first question is no, so there is no need to address your second question. The purpose of the MOU was not to shift any responsibilities between the Agencies. Rather, it was to help facilitate effective coordination of our respective legal authorities. Under the Safe Drinking Water Act (SDWA), EPA is the lead federal agency with responsibility to regulate the safety of public water supplies. EPA does not have responsibility for substances added to water solely for preventative health care purposes, such as fluoride, other than to limit the addition of such substances to protect public health or to prevent such substances from interfering with the effectiveness of any required treatment techniques. SDWA Section 1412(b)(11); see also A Legislative History of the Safe Drinking Water Act, Committee Print, 97th Cong, 2d Session (February 1982) at 547. The Department of Health and Human Services (HHS), acting through the FDA, remains responsible for regulating the addition of drugs to water supplies for health care purposes.

The 1979 MOU was intended to address contamination of drinking water supplies as a result of direct or indirect additives to drinking water, not to address the addition of substances solely for preventative health purposes. 44 Fed. Reg. 42775 (July 20, 1979) ("EPA and FDA agree: (1) that *contamination* of drinking water from the use and application of direct and indirect additives and other substances poses a potential public health problem...")(emphasis added). It was intended to avoid potentially duplicative regulation of "food", which FDA had, in the past, considered to include drinking water. 44 Fed. Reg. 42775 (July 20, 1979). The MOU did not address drugs or other substances added to water for health care purposes.

A-8
AH.38

I hope that this has adequately answered your inquiry. Please do not hesitate to contact Carrie Wehling of my staff (202-564-5492) if you have further questions about this.

Sincerely,

Steven M. Neugeboren
Associate General Counsel
Water Law Office

A-9
AH.39

GERALD STEEL, PE
ATTORNEY-AT-LAW
7303 YOUNG ROAD NW
OLYMPIA, WA 98502
Tel/fax (360) 867-1166

January 23, 2015

Thinh X. Nguyen, Director
Office of Combination Products
WO Bldg. 2, Room 5129
10903 New Hampshire Ave
Silver Spring, MD 20993

RE: Request for Review pursuant to 21 CFR 10.75
Request for Reconsideration pursuant to 21 CFR 3.8(c)
Regarding Six Requests for Designation for Libera Bottled Fluoridated Water

Dear Thinh X. Nguyen:

On January 13, 2015, I submitted on behalf of Mike Libera, six Requests for Designation for bottled fluoridated water manufactured by compounding purchased municipal water with one of three fluoridation chemicals and labeling the bottles with either an explicit or implicit drug claim. The proposed explicit drug claim is, "This drinking water is intended for use in the prevention of tooth decay disease." Attachment 1 hereto is a copy of the transmission email I sent to OC Combination Products along with the email from Dr. Moreno, a biologist, acknowledging receipt of the six RFDs.

Attachment 2 hereto is one of the three nearly-identical responses received from Dr. Moreno on January 20, 2015 and Attachment 3 hereto is one of the three nearly-identical replies I sent to Dr. Moreno on January 20, 2015. The five working day deadline for OC Combination Products to return any RFD "determined to be incomplete" along "with a request for the missing information" was on January 21, 2015. Nothing further was provided to me..

Dr. Moreno deviates from 21 CFR Part 3 in that, under the circumstances, he failed to find the six RFDs complete and provide the filing date. In his January 20, 2015 email, Dr. Moreno misinterprets 21 CFR Part 3 which states in 21 CFR 3.3 that Part 3 "applies to: a) Any combination product, or *b) Any product where the agency component with primary jurisdiction is unclear or in dispute.*" (Emphasis supplied.) This subsection 3.3(b) is applicable. We believe that caselaw is clear that bottled mineral water with an explicit drug claim is regulated as a drug by CDER. (Attachment 3 hereto.) That this issue is unclear or in dispute is evident by the response from Dr. Moreno which suggests that our product may be a food. (Attachment 2 hereto.)

Att. 40

As the "purpose" section of Part 3 states, there is a:

> second purpose of this regulation . . . by providing procedures for determining which agency component will have primary jurisdiction for any drug . . . where such jurisdiction is unclear or in dispute.

(21 CFR 3.1.) Part 3 also states:

> [F]or a product where the agency component with primary jurisdiction is unclear or in dispute, the sponsor of an application for premarket review should follow the procedures in [section] 3.7 to request a designation of the agency component with primary jurisdiction before submitting the application.

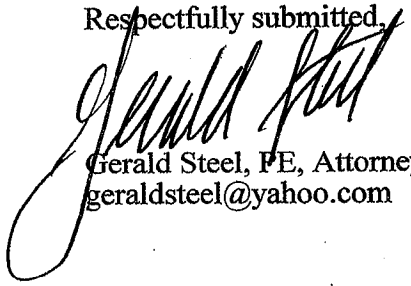
(21 CFR 3.5(b).)

We have followed the procedures in 21 CFR 3.7 in submitting our six RFDs. We have recommended that your Office respond by finding that FDA CDER has jurisdiction over Libera Bottled Fluoridated Water when the bottles are labeled with an explicit or implicit drug claim.

We are aware that CFSAN has approved sale of bottled fluoridated water with a health claim which is appropriate when the product remains a food. There is an approved health claim: "Drinking fluoridated water may reduce the risk of [dental caries or tooth decay]. http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm073602.htm Libera does not want to market his products with a health claim. He see the opportunity to market his products with the stronger drug claim, "This drinking water is intended for use in the prevention of tooth decay disease." As you may know, a majority of people in the U.S. drink fluoridated tap water because they believe this fluoridated water will reduce and prevent tooth decay disease. Libera can provide a product in interstate commerce that gives the people who don't have fluoridated tap water the option to buy fluoridated drinking water that is approved by FDA to prevent tooth decay. This is a powerful marketing tool. Of course, as stated in the RFDs, Libera would only make fluoridated bottled water if the FDA found it safe and effective in the prevention of dental caries disease. Only FDA CDER (or HHS) can make this determination and so we request that your Office respond by finding that FDA CDER has jurisdiction over bottled fluoridated water when the labels make a drug claim.

We submit this letter under 21 CFR 10.75 to request that you review the decisions made by Dr. Milone in the three 1/20/15 emails concerning the six RFDs for Libera Bottled Fluoridated Water and also, if appropriate, under 21 CFR 3.8(c) for reconsideration of his decisions. We believe that our RFDs should be filed, and discussions held with CDER to determine if the products will be regulated as drugs.

Respectfully submitted,



Gerald Steel, PE, Attorney at Law
geraldsteel@yahoo.com

Attachments: A-1 to A-3

AH. 41

Gerald Steel

From: OC Combination Products [Combination@FDA.GOV]
Sent: Tuesday, January 13, 2015 3:51 PM
To: Gerald Steel
Cc: OC Combination Products
Subject: RE: Submittal of Six Requests for Designation for Libera Bottled Fluoridated Water - Two using Sodium Fluorosilicate attached

Dear Mr. Steel,

Thank you for contacting the Office of Combination Products. Your six RFD's were received on January 13th, 2015. They will be screened for completeness in accordance with 21 CFR 3.8(a). You will be notified by email whether each of the RFD's have been accepted for review, and if not, what additional information would need to be provided in a new RFD.

Jose L. Moreno Ph.D.

Office of Combination Products
Office of Special Medical Programs
Food and Drug Administration

From: Gerald Steel [mailto:geraldsteel@yahoo.com]
Sent: Tuesday, January 13, 2015 3:47 PM
To: OC Combination Products
Subject: Submittal of Six Requests for Designation for Libera Bottled Fluoridated Water - Two using Sodium Fluorosilicate attached

Ms. Lauritsen and Ms. Larson and other staff,

Today I am mailing, in a single package, the original and two copies each of six Requests for Designation for Libera Bottled Fluoridated Water. With this email I will submit electronic copies of two of the Requests for Designation that both make the bottled fluoridated water by privately adding Sodium Fluorosilicate to unfluoridated water obtained from a city public water system and then putting this water (at least initially) in one gallon bottles. The difference between these two requests is that one request labels the bottles with what is clearly a drug claim and the other request labels the bottles with what we claim is an implied drug claim. I will submit electronic copies of the other four Requests for Designation by two separate emails. I look forward to hearing back from you.

A-1
AH.42

Gerald Steel

From: OC Combination Products [Combination@FDA.GOV]
Sent: Tuesday, January 20, 2015 1:57 PM
To: Gerald Steel; OC Combination Products
Cc: Hayes, Leigh
Subject: RE: Submittal of Six Requests for Designation for Libera Bottled Fluoridated Water - Two using Sodium Fluoride attached

Dear Mr. Steel,

This email is in response to your six submissions dated January 13, 2015, regarding bottled fluoridated water. 21 CFR Part 3 addresses requests for designation for products that would be regulated by FDA's Center for Drug Evaluation for Research, the Center for Devices and Radiological Health, or the Center for Biologics Evaluation and Research. Jurisdictional questions concerning a product that may be within the jurisdiction of the Center for Food Safety and Applied Nutrition (CFSAN) are outside the scope of 21 CFR Part 3 and section 563 of the FD&C Act. Bottled water is generally regulated by CFSAN as a food. Accordingly, we are treating your submissions not as requests for designation under 21 CFR Part 3 and section 563 of the FD&C Act but instead as informal inquiries to the Agency, and FDA will be reaching out to you concerning these inquiries.

Sincerely,

Joseph Milone, PhD
Office of Combination Products
Office of Special Medical Programs
Food and Drug Administration

From: Gerald Steel [mailto:geraldsteel@yahoo.com]
Sent: Tuesday, January 13, 2015 3:40 PM
To: OC Combination Products
Subject: Submittal of Six Requests for Designation for Libera Bottled Fluoridated Water - Two using Sodium Fluoride attached

Ms. Lauritsen and Ms. Larson and other staff,

Today I am mailing, in a single package, the original and two copies each of six Requests for Designation for Libera Bottled Fluoridated Water. With this email I will submit electronic copies of two of the Requests for Designation that both make the bottled fluoridated water by privately adding Sodium Fluoride to unfluoridated water obtained from a city public water system and then putting this water (at least initially) in one gallon bottles. The difference between these two requests is that one request labels the bottles with what is clearly a drug claim and the other request labels the bottles with what we claim is an implied drug claim. I will submit electronic copies of the other four Requests for Designation by two separate emails. I look forward to hearing back from you.

Gerald Steel
Attorney at Law
7303 Young Rd. NW

A-2
AH. 43

Gerald Steel

From: Gerald Steel [geraldsteel@yahoo.com]
Sent: Tuesday, January 20, 2015 6:40 PM
To: 'OC Combination Products'
Cc: 'Hayes, Leigh'
Subject: RE: Submittal of Six Requests for Designation for Libera Bottled Fluoridated Water - Two using Sodium Fluoride attached

Dr. Milone,

Your response below is not acceptable to my client and me. While I understand that bottled water is generally regulated by CFSAN as a food, we are proposing an explicit (and as a second request - an implicit) drug claim on the label of our products. Our products will be distributed in interstate commerce. As such we have recommended that the products be considered drugs by FDA's CDER. You do not have our permission to treat our submission as an informal inquiry to the FDA. We have made a proper submittal under 21 CFR Part 3 and as such we demand a response within 5 working days as to whether our application is complete and filed. Our position is strongly supported by caselaw. We provide the following quote from *Hanson v. United States*, 417 F.Supp. 30, 34-35 (D.Minn. 1976):

[QUOTE]
"The word 'drug' is defined in 21 U.S.C. s 321(g)(1) to include: ' . . . (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals . . ..' (emphasis supplied [in original]). Countless court decisions emphasize that it is the intended use of an article which determines whether or not it is a 'drug,' and that even the most commonly ingested foods and liquids are 'drugs' within the meaning of the Act if the intended use of such articles when distributed in interstate commerce falls within the definition of s 321(g)(1). See, e. g., *Kordel v. United States*, 335 U.S. 345, 69 S.Ct. 106, 93 L.Ed. 52 (1948) (compounds of minerals, vitamins, and herbs); *Seven Cases v. United States*, 239 U.S. 510, 518, 36 S.Ct. 190, 60 L.Ed. 411 (1916) (alcoholic solution); *United States v. Millpax, Inc.*, 313 F.2d 152, 153-54 (7th Cir. 1963), *cert. denied*, 373 U.S. 903, 83 S.Ct. 1291, 10 L.Ed.2d 198 (1963) 417 F.Supp. 35 ('iron tonic'); *United States v. Hohensee*, 243 F.2d 367 (3d Cir. 1957), *cert. denied*, 353 U.S. 976, 77 S.Ct. 1058, 1 L.Ed.2d 1136 (1957) ('health foods'); *Bradley v. United States*, 264 F. 79 (5th Cir. 1920) (mineral water); *United States v. Vitasafe Formula M*, 226 F.Supp. 266, 278 (D.N.J.1964), *remanded on other grounds*, 345 F.2d 864 (3d Cir. 1965), *cert. denied*, 382 U.S. 918, 86 S.Ct. 290, 15 L.Ed.2d 232 (1965) (vitamin and mineral capsules); *United States v. 250 Jars . . . Fancy Pure Honey*, 218 F.Supp. 208, 211 (E.D.Mich.1963), *aff'd* 344 F.2d 288 (6th Cir. 1965) (honey); *United States v. 46 Cartons . . . Fairfax Cigarettes*, 113 F.Supp. 336, 338 (D.N.J.1953) (cigarettes). From these cases, it is apparent that the plaintiffs' argument that laetrile is a 'vitamin' or a food does not preclude its being a drug if the tablets and vials at issue here are peddled for the intended uses set forth in the statute. It is also well established that the 'intended use' of a product, within the meaning of the Act, is determined from its label, accompanying labeling, promotional claims, advertising, and any other relevant source. See, e. g., *United States v. An Article . . . Sudden Change*, 409 F.2d 734, 739 (2d Cir. 1969) (advertisements in various media); *United States v. Millpax, Inc.*, supra, at 154-55 (letters and oral representations); *Nature Food Centres, Inc. v. United States*, 310 F.2d 67 (1st Cir. 1962), *cert. denied*, 371 U.S. 968, 83 S.Ct. 552, 9 L.Ed.2d 539 (1963) (speeches at public lecture hall); V. *E. Irons, Inc. v. United States*, 244 F.2d 34 (1st Cir.), *cert. denied*, 354 U.S. 923, 77 S.Ct. 1383, 1 L.Ed.2d 1437 (1957) (statements of an authorized distributor); *United States v. Articles of Drug . . . Food Plus, Inc.*, 239 F.Supp. 465 (D.N.J.1965), *remanded on other grounds*, 362 F.2d 923 (3d Cir. 1966) (radio broadcast)."
[END QUOTE]

In *Bradley v. United States*, 264 F. 79, 81-82 (5th Cir. 1920) the Court explicitly found that bottled mineral water is a drug when there is a drug claim on the label. Therefore, we consider it settled law that bottled water is a drug when there is a drug claim on the label. We will consider your action to be frivolous if you do not process our Requests for Designations as required by 21 CFR Part 3. Our Requests for Designations are not informal inquiries to FDA.

Gerald Steel PE

A-3
AR. 44

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Office of Combination Products
WO 32, Room 5129
10903 New Hampshire Avenue
Silver Spring, MD 20993

March 23, 2015

Mr. Gerald Steel, PE
Attorney-At-Law
7303 Young Road, NW
Olympia, WA 98502

Re: Request for Review under 21 CFR 10.75 ("10.75 Request")
and Request for Reconsideration pursuant to 21 CFR 3.8(c) regarding Libera Bottled Fluoridated Water Requests for Designation
Dated: January 23, 2015
Received: February 9, 2015

Dear Mr. Steel:

This letter is in response to your January 23, 2015 Request for Review under 21 CFR 10.75 ("10.75 Request") and Request for Reconsideration pursuant to 21 CFR 3.8(c) regarding Six Requests for Designation for Libera Bottled Fluoridated Water (RFR) you submitted on January 13, 2015. In that letter you requested review under 21 CFR 10.75 of Dr. Joseph Milone's January 20, 2015, response that the six Requests for Designation (RFDs) submitted regarding Libera Bottled Water would be treated by the Office of Combination Products as informal inquiries because they fall outside the scope of 21 CFR Part 3 and that those inquiries would be referred to the Center for Food Safety and Applied Nutrition. On January 20, 2015, you replied to Dr. Milone's January 20, 2015, response, and he provided an additional response on January 26, 2015.

I have reviewed your 10.75 Request and the administrative file for the decision regarding your request. In your 10.75 request, you argue that Dr. Milone misinterpreted 21 CFR Part 3 when he determined that your inquiries fell outside the scope of Part 3.

Att. 45

As Dr. Milone noted in his email dated January 26, 2015, his response to your inquiries was intended to address the threshold question regarding whether submitting a Request for Designation under 21 CFR Part 3 is the appropriate procedure regarding a determination of jurisdiction of your proposed products. It was not intended to make any determination regarding whether your proposed products are foods or drugs.

I find your arguments regarding the scope of 21 CFR Part 3 unpersuasive. As Dr. Milone's email noted, 21 CFR part 3 "does not apply to foods, veterinary products, or cosmetics." 56 FR 58754. Therefore, jurisdictional questions concerning a product that may be within the jurisdiction of the Center for Food Safety and Applied Nutrition (CFSAN) are outside the scope of 21 CFR Part 3 and section 563 of the FD&C Act. Your requests involve whether the proposed products are foods or drugs. Because your requests fall outside the scope of the regulation and statutory provision that authorize requests for designation, your submissions regarding fluoridated bottled water were properly treated not as requests for designation but as informal inquiries to the Agency.

Therefore, I affirm Dr. Milone's decision to refer your inquiries to CFSAN. In addition, because your inquiries are outside the scope of 21 CFR Part 3, your inquiries are also outside the scope of 21 CFR 3.8(c) governing requests for reconsideration. Accordingly, Dr. Milone's January 20, 2015, response will not be reviewed under that regulation.

Sincerely,

Thinh X. Nguyen

Director, Office of Combination Products

AH. 46