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.

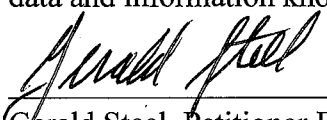
C. ***Environmental Impact***

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.



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