Bill Osmunson DDS, MPH
President, Washington Action for Safe Water
1418 – 112th Ave NE
Bellevue Washington 98004
425.466.0100
bill@teachingsmiles.com

June 14, 2010

National Freedom of Information Officer
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW (2822T)
Washington, DC 20460
(202) 566-1667 FAX (202) 566-2147
E-mail: **hq.foia@epa.gov**

Re: Freedom of Information Act Request

Dear Sir or Madam:

This is a request under the Freedom of Information Act for the following information to be provided to me:

#1. A digital copy of the EPA's equivalent of the FDA's New Drug Approval process for the fluoridation drug when used at 0.8 ppm to 1.2 ppm in public water, to include EPA's required documentation for chemistry, nonclinical pharmacology and toxicology, human pharmacokinetics and bioavailability, clinical microbiology, clinicals, safety, statistics, case report tabulations, patient information on any patient claims, patient certification, establishment descriptions, and required drug legend.

#2. A digital copy of records, reports, papers, meeting minutes, correspondence or clarifications of the MOU 225079-2001 http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm116216.htm between the EPA and FDA. And any records further clarifying the intent of the MOU 225079-2001 or another MOU as to whether the EPA is permitted to approve the sale and use of substances defined as drugs by the FD&C Act, when the substance is added to public water.

#3. Records the EPA has of Congressional Authority which exempts drugs when added to public water from the New Drug Application regulatory process and FD&C Act and provides the EPA with authority to approve drugs when they are added to public water.

In order to help to determine my status for purposes of determining the applicability of any fees, you should know that I am the President of Washington Action, not for profit, and I request a waiver of all fees for this request.

Disclosure of the requested information to me is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not in our commercial interest. The information will be used in creating new regulations for water safety in Washington State.

If fees cannot be waved, please provide a list of documents and the costs associated with each.

I request that the information I seek be provided in electronic format, and I would like to receive it on a personal computer disk or a CD-ROM or email to bill@teachingsmiles.com or US postal service to the address below.

Thank you for your consideration of this request.

Sincerely,

Bill Osmunson DDS, MPH
President, Washington Action for Safe Water
1418 – 112th Ave NE
Bellevue Washington 98004
425.466.0100
bill@teachingsmiles.com

cc Ned Therien, WBOH ned.therien@doh.wa.gov

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

JUL - 6 2010

OFFICE OF WATER

Mr. Bill Osmunson
President
Washington Action for Safe Water
1418 112th Avenue, N.E.
Bellevue, Washington 98004

Re: Freedom of Information Act Request HQ-FOI-01418-10

Dear Mr. Osmunson:

This is in response to your Freedom of Information Act request of June 14, 2010. I wish to advise you that the Office of Water has no records responsive to your request. This is not a denial.

You may appeal this no records response to the National Freedom of Information Officer, U.S. Environmental Protection Agency (EPA), FOIA and Privacy Branch, 1200 Pennsylvania Avenue, N.W. (2822T), Washington, DC 20460 (U.S. Postal Service Only), FAX: (202) 566-2147, E-mail: hq.foia@epa.gov. Only items mailed through the United States Postal Service may be delivered to 1200 Pennsylvania Avenue, NW. If you are submitting your appeal via hand delivery, courier service or overnight delivery, you must address your correspondence to 1301 Constitution Avenue, N.W., Room 6416J, Washington, DC 20004. Your appeal must be made in writing, and it must be submitted no later than 30 calendar days from the date of this letter. The Agency will not consider appeals received after the 30 calendar day limit. The appeal letter should include the FOI listed above. For quickest possible handling, the appeal letter and its envelope should be marked "Freedom of Information Act Appeal."

The Safe Drinking Water Act prohibits the deliberate addition of any substance to drinking water for health-related purposes other than disinfection of the water. Decisions on whether or not to fluoridate drinking water are made at a state or local level and are not in violation of the EPA Maximum Contaminant Level for fluoride (4 mg/L). The certification of fluoridation chemicals for use in National Public Drinking Water Systems is conducted by independent organizations accredited by the American

National Standards Institute (ANSI) to certify drinking water additives against NSF International Standards/ANSI Standard 60: Drinking Water Treatment Chemicals: Health Effects. The states require that the chemicals used by drinking water treatment facilities be certified against Standard 60. These requirements are independent of the U.S. EPA .

Sincerely,

6/30/2010

Elizabeth Behl, Acting Chief
Health and Ecological Criteria Division
Office of Science and Technology

Bill Osmunson DDS, MPH
President, Washington Action for Safe Water
1418 – 112th Ave NE
Bellevue Washington 98004
425.466.0100
bill@teachingsmiles.com

June 14, 2010

CDC/ATSDR
Attn: FOIA Office, MS-D54
1600 Clifton Road, NE
Atlanta, GA 30333
Fax 404-498-1575
FOIARequests@cdc.gov

Re: Freedom of Information Act Request

Dear Sir or Madam:

The Washington State Board of Health references the Centers for Disease Control as recommending the use of fluoride in public water for the prevention of dental decay.

This is a request under the Freedom of Information Act for the following information to be provided to me:

#1. Because the FDA has not approved the fluoridation drug, I am requesting a digital copy of the CDC's approval process for fluoridation, equivalent to the FDA's New Drug Approval process, to include CDC's records such as chemistry, nonclinical pharmacology and toxicology, human pharmacokinetics and bioavailability, clinical microbiology, clinicals, safety, statistics, case report tabulations, patient information on any patient claims, patient certification, establishment descriptions, total individual exposure for both the average population and subgroups above the 95th percentile, and drug legend.

#2. Fluoride when ingested with the intent to prevent decay is defined by the FD&C Act as a drug. Please provide records the CDC has which authorizes the CDC to recommend unapproved, illegal drugs?

#3. What supporting empirical data and randomized controlled trials on both safety and/or efficacy does the CDC have to support recommending public tap water be fluoridated to an "optimal" target concentration of 0.7-1.2 ppm to help prevent cavities?

#3. What scientific evidence of randomized controlled trials does the CDC have to support the statement that fluoridation is one of the ten great public health achievements of the 20th Century?

#4. William Bailey, DDS, MPH of the CDC told Ned Therien of the Washington State Board of Health that "CDC is continually reviewing data regarding the "optimal" level and safety of tap water fluoridation." Please provide me a copy of the empirical evidence, randomized controlled trials, evidence based analysis, and/or references the CDC has on each of the following:

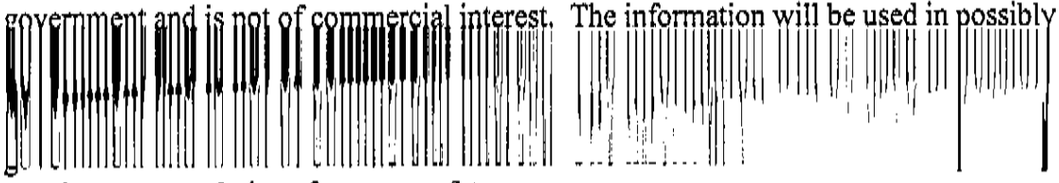
a. total median exposure and exposure levels for the 99th percentile of the population,
b. recommended dosage levels for all age groups,
c. efficacy exposure levels for all age groups,
d. recommended safety for thyroid,
e. safety levels for infants with minimal iodine intake,
f. carcinogenicity studies for all age groups, genders and age groups,
g. bone fracture safety for the elderly,
h. tooth fracture safety,
i. IQ safety,
j. dental fluorosis safety,
k. kidney safety,
l. Downs syndrome safety,
m. Pharmacokinetics safety,
n. dates, times, names of participants and minutes from the meetings of these ongoing reviews of safety
o. costs of dental treatment savings with fluoridation.

#5. The Washington State Board of Health has stated, "CDC states that the 2006 National Research Council report supports CDC's recommended "optimal" fluoridation levels as being safe." What records does the CDC have that the NRC 2006 supports the addition of fluoride at 1 ppm when they concluded, "In light of the collective evidence on various health end points and total exposure to fluoride, the committee concludes that EPA's MCLG of 4 mg/L should be lowered" and several studies of harm were at fluoridation levels.

#6. The CDC claims the compounds used for fluoridation are high purity. Please provide records the CDC has on the purity of the compounds, names of countries fluoride comes from for use in our public water and name of their product and company, and records of purity test results of these compounds.

In order to help to determine my status for purposes of determining the applicability of any fees, as President of Washington Action for Safe Water a not for profit company, I request a waiver of all fees for this request.

Disclosure of the requested information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not of commercial interest. The information will be used in possibly



creating new regulations for water safety.

If fees cannot be waved, please provide a list of documents and the costs associated with each.

I request that the information I seek be provided in electronic format, and I would like to receive it on a personal computer disk or a CD-ROM or email to bill@teachingsmiles.com or US postal service to the address below.

Thank you for your consideration of this request.

Sincerely,

Bill Osmunson DDS, MPH
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Bellevue Washington 98004
425.466.0100
bill@teachingsmiles.com

cc Ned Therien, WBOH ned.therien@doh.wa.gov
cc William Bailey wdb9@cdc.gov

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

June 16, 2010

Bill Osmunson
1418 112th Ave NE
Bellevue, WA 98004

Dear Mr. Osmunson:

This letter is in response to your Freedom of Information Act (FOIA) request of June 15, 2010.

Your Freedom of Information Act request has been received by the Centers for Disease Control and Prevention (CDC)/Agency for Toxic Substances and Disease Registry (ATSDR) and will be sent to the area(s) which may have pertinent records. Program officials will initiate a search, and we will provide a copy of all releasable agency records as quickly as possible. The cut-off date for your request will be the date the search for responsive records is initiated by program staff. All requests are handled on a first-in, first-out basis.

We will address your request for a fee waiver when we ascertain from program staff that the cost of the billable FOIA services will exceed the Agency's threshold.

Your request has been assigned #10-00870-FOIA. You may check on the status of your case by going to our FOIA webpage at http://www2a.cdc.gov/od/foiastatus and entering this number. The fiscal year is the first two numbers and the request ID is the second set of numbers.

Sincerely,

Freedom of Information Act Office
Office of the Chief Information Officer
(404) 498-1580
Fax line (404 498-1575

Re: water fluoridation

Bill Osmunson DDS, MPH
President, Washington Action for Safe Water
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June 14, 2010

Food and Drug Administration
Frederick J. Sadler
Director, FOI Staff
5600 Fishers Lane (HFI-30)
Rockville, MD 20857 telephone number: (301) 827-6567 fax number: (301) 443-1726

Re: Freedom of Information Act Request

Dear Sir:

This is a request under the Freedom of Information Act for the following information to be provided to me:

#1. Records (digital if possible) of the e-mail exchange on or about May 21, 2010, between Ned Therien and John V. Kelsey, DDS, MBA, Dental Team Leader, Division of Dermatology and Dental Products, FDA. These emails appear to indicate that the "FDA has relinquished any authority it might have for regulating fluoride levels in tap water under the memorandum of understanding with EPA." (WBOH)

#2. Records, reports, papers, meeting minutes, correspondence with dates and names and/or clarifications of the MOU 225079-2001 http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm116216.htm between the EPA and FDA.

#3. Records available providing Congressional approval for the FDA to relinquish drug regulatory approval (NDA) for fluoride in drinking water when the substance is intended to prevent disease and defined by the FD&C Act as a drug.

#4. Records the FDA has available providing Congressional approval for the EPA to assume jurisdiction and authority for the responsibility of substances intended to prevent disease when sold in public water systems. Which action by the EPA would appear to be in stated violation of the Safe Drinking Water Act.

#5. Records of whether the MOU 225079-2001 is intended to only apply to substances to make water safe and for foods as stated in the MOU, or whether the MOU includes drugs, substances used with the intent to prevent disease.

#6. To include any records, action, minutes of meetings, reports, conclusions, lists of literature research, names of senior FDA toxicologists, past and current, assisting the EPA and/or correspondence the FDA has regarding assistance to the EPA under the MOU related to toxicological decision. In other words, records that the following MOU terms of agreement have and are being met. MOU "III. Terms of Agreement: (B)(2)(a, b, c)" providing "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".

#7. Records the FDA has of Congressional Authority which exempts drugs when combined with public water from the New Drug Application regulatory process and FD&C Act and authorizes the FDA to relinquish drug regulatory jurisdiction.

#8. Records of whether the MOU 225079-2001 was between the Food section or Drug section of the FDA and the EPA.

In order to help to determine my status for purposes of determining the applicability of any fees, you should know that I am the President of Washington Action for Safe Water, not for profit, and I request a waiver of all fees for this request.

Disclosure of the requested information to me is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not in our commercial interest. The information will be used in creating new regulations for water safety in Washington State.

If fees cannot be waved, please provide a list of documents and the costs associated with each. I request that the information I seek be provided in electronic format, and I would like to receive it on a personal computer disk or a CD-ROM or email to bill@teachingsmiles.com or US postal service to the address below.

Thank you for your consideration of this request.

Sincerely,

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Bellevue Washington 98004
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bill@teachingsmiles.com

Faxed to FDA 301-443-1726 or 301-443-1719
cc Ned Therien, WBOH ned.therien@doh.wa.gov
John V. Kelsey, DDS, MBA, FDA john.kelsey@fda.hhs.gov

FDA U.S. Food and Drug Administration

News & Events

Regulation of Bottled Water

Statement of

Joshua M. Sharfstein, M.D.
Principal Deputy Commissioner of Food and Drugs
Food and Drug Administration
Department of Health and Human Services

before

the Subcommittee on Oversight and Investigations
House Committee on Energy and Commerce

July 8, 2009

INTRODUCTION

Good morning Mr. Chairman and Members of the Subcommittee. I am Joshua Sharfstein, Principal Deputy Commissioner of Food and Drugs at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). Thank you for the opportunity to discuss with you today the regulation of bottled water.

Bottled water is an increasingly popular beverage. According to the Beverage Marketing Corporation, the amount of bottled water consumed in the United States has doubled over the past 10 years. Specifically, between 1998 and 2008, the average per capita consumption of bottled water has increased from 14.7 to 28.5 gallons.

A possible indicator of bottled water's popularity is the volume of questions about bottled water coming into FDA's regulatory and consumer information staff. People frequently contact us to ask questions such as: Who regulates bottled water? How is it regulated? Is bottled water tested and inspected? My testimony will summarize FDA's approach to regulating bottled water. I will cover such topics as our legal authority to regulate bottled water, what regulations and guidance are in place, and inspections.

FDA REGULATION OF BOTTLED WATER

In the United States, bottled water and tap water are regulated by two different agencies: FDA regulates bottled water and the Environmental Protection Agency (EPA) regulates tap water, also referred to as municipal water or public drinking water. EPA's Office of Ground Water and Drinking Water has issued extensive regulations on the production, distribution and quality of public drinking water, including regulations on source water protection, operation of drinking water systems, contaminant levels, and reporting requirements.

Under our statutory authority, FDA regulates bottled water as a food. The Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act) provides FDA with broad regulatory authority over food that is introduced or delivered into interstate commerce. Under the FD&C Act, manufacturers are responsible for producing safe, wholesome and truthfully labeled food products, including bottled water products. It is a violation of the law to introduce into interstate commerce adulterated or misbranded products that violate the various provisions of the Act.

FDA has established specific regulations for bottled water in Title 21 of the Code of Federal Regulations (21 CFR). These regulations include standard of identity regulations in 21 CFR § 165.110(a), that define different types of bottled water, such as spring water and mineral water, and standard of quality regulations in 21 CFR § 165.110(b), that establish allowable levels for chemical, physical, microbial and radiological contaminants in bottled water. FDA also has established current Good Manufacturing Practice (cGMP) regulations for the processing and bottling of bottled drinking water in 21 CFR part 129. Labeling regulations (21 CFR part 101) and cGMP regulations (21 CFR part 110) for foods in general also apply to bottled water.

Current Good Manufacturing Practice Regulations -- These regulations require that bottled water be safe and that it be processed, bottled, held and transported under sanitary conditions. Processing practices addressed in the cGMP regulations include protection of the water source from contamination, sanitation at the bottling facility, quality control to ensure the bacteriological and chemical safety of the water, and sampling and testing of source water and the final product for microbiological, chemical, and radiological contaminants. Bottlers are required to maintain source approval and testing records to show to government inspectors. Checking adherence to part 129 regulations is an important part of FDA inspections of bottled water plants.

Standard of Identity Regulations -- Under the standards of identity regulation at 21 CFR 165.110(a), FDA defines bottled water as water that is intended for human consumption and that is sealed in bottles or other containers, with no added ingredients except that it may contain safe and suitable antimicrobial agents. Fluoride also may be added within the limits set by FDA. The name of the food is "bottled water" or "drinking water." FDA also has defined various other types of bottled water, such as "artesian water," "artesian well water," "ground water," "mineral water," "purified water," "sparkling bottled water," and "spring water."

Bottled water labeled with any of these terms must meet the appropriate definitions under the standard of identity or it will be considered misbranded under the FD&C Act. For example, a bottle labeled as containing "mineral water" must meet the following criteria, among others: the water must contain no less than 250 parts per million (ppm) total dissolved solids; it must come from a geologically and physically protected underground water source; and it must contain no added minerals. "Mineral water" also must have a constant level and relative proportions of minerals and trace elements at the point of emergence from the source, with due account being taken of natural fluctuation cycles. FDA established its definitions for different types of bottled water in 1995. These preempted state definitions existing at that time, some of which varied from state to state. We have provided, in an appendix to our testimony, a table which provides several of these definitions.

Standard of Quality Regulations -- Under the standard of quality regulation at 21 CFR 165.110(b), FDA establishes allowable levels for contaminants in bottled water. There are microbiological standards that set allowable coliform levels; physical standards that set allowable levels for turbidity, color and odor; and radiological standards that set levels for radium-226 and radium-228 activity, alpha-particle activity, beta particle and photon radioactivity, and uranium. The standard of quality also includes allowable levels for more than 70 different chemical contaminants.

Section 165.110(b) also lists methods that FDA will use to determine whether bottled water samples comply with the quality standard. Bottlers are not required to use these methods in their own facilities; alternate methods are acceptable. Whatever method they use, bottlers are responsible

for ensuring that their bottled water can pass the tests used by FDA in its own laboratories, should testing be performed by FDA.

What happens if bottled water contains a substance at a level greater than that allowed under the quality standard? Section 165.110(c) states that when the microbiological, physical, chemical or radiological quality of bottled water is below that prescribed in the quality standard, the label of the bottled water bottle must contain a statement of substandard quality such as "Contains Excessive Bromate," "Contains Excessive Bacteria," or "Excessively Radioactive." Such labels solely indicate to the consumer that a quality standard has not been met. We are not aware of firms that currently are availing themselves of their option to use such a disclaimer on the label. Even if such a labeling statement is used, labels cannot be used to ameliorate food safety deficiencies. Regardless of whether bottled water bears a statement of substandard quality, it is considered adulterated if it contains a substance at a level considered injurious to health under section 402(a)(1) of the FD&C Act.

Another noteworthy point about section 165.110 is that it allows for the use of safe and suitable antimicrobial agents such as ozone. FDA does not specifically require that bottlers use antimicrobial agents in bottled water as long as the water is safe for human consumption.

Inspection of Bottled Water Plants

FDA monitors and inspects bottled water products and processing plants as part of its general food safety program. Because FDA's experience over the years has shown that bottled water has a good safety record, bottled water plants generally are assigned a relatively low priority for inspection. The Agency, however, inspects violative firms more frequently, depending on the number, significance and recurrence of violations. In addition, FDA's field offices follow up on consumer and trade complaints and other leads, as appropriate, on potentially violative bottled water products.

In Fiscal Years (FY) 2007 and 2008, FDA and state agencies under contract to FDA conducted 412 and 468 inspections of bottled water facilities, respectively. In the first nine months of FY 2009, FDA and state contract agencies have conducted 253 inspections.

Information about what FDA inspectors look for during inspections generally is found in the Investigations Operations Manual published by FDA's Office of Regulatory Affairs (ORA), and more detailed information about inspections of bottled water facilities is found in the Guide to Inspections of Manufacturers of Miscellaneous Food Products, Volume II. Specific items mentioned in the inspection guide for bottled water establishments include: 1) verifying that the plant's product water and operational water supply are obtained from an approved source; 2) checking whether any source claims on the label comply with the definitions in 21 CFR 165.110(a); 3) inspecting washing and sanitizing procedures; 4) inspecting the filling, capping, and sealing operations; and 5) determining whether the firms analyze their source water and product water for the chemical and microbiological contaminants listed in 21 CFR 165.110(b), according to the required schedules.

Sampling and Testing

As with other types of food, FDA periodically collects and analyzes samples of bottled water. Samples come from several different sources. Some samples are collected during inspections if the inspector's observations warrant collection to test for contaminants or if the bottled water facility has a previous history of contamination. Other samples are collected in response to trade or consumer complaints. Finally, samples of foreign bottled water products offered for entry into the United States may be collected and tested to determine if they are in compliance with all applicable U.S. laws and FDA regulations.

FDA laboratories may test the water for microbiological, radiological or chemical contamination. Individual samples are not tested for all possible contaminants cited in the quality standard, but for selected contaminants, depending on the reason for the sampling. For example, suspected microbiological contamination may result in microbiological analysis. (However, as noted, bottlers are required to maintain testing records to show to government inspectors for all the contaminants in the quality standard.) FDA also may review the labeling on bottled water samples.

State and Local Regulations

In addition to FDA, state and local governments also regulate bottled water. FDA relies on state and local government agencies to approve water sources for safety and sanitary quality, as specified in part 129.3(a). The International Bottled Water Association (IBWA) also has developed a model code of regulations that its members must follow.

Developing New FDA Regulations

It is important to note that under section 410 of the FD&C Act, FDA must follow specific instructions on establishing quality standard regulations for bottled water in response to regulatory developments at EPA concerning public drinking water.

Under section 410, when EPA establishes new maximum contaminant levels (MCL) or treatment techniques for contaminants in public drinking water as part of a National Primary Drinking Water Regulation (NPDWR), FDA is required to establish a standard of quality regulation for the same contaminants in bottled water, or to make a finding that such a regulation is not necessary to protect the public health because the contaminant is not present in water used for bottled drinking water. For treatment techniques, section 410 requires that bottled water be subject to requirements no less protective of the public health than those applicable to water from public water systems using the techniques required by EPA's NPDWRs. If FDA adopts an allowable level under the quality standard regulations, the level in bottled water must be no less stringent than EPA's MCL for drinking water; FDA's regulation must have the same effective date as EPA's regulation and be published no later than 180 days before the effective date.

FDA has generally adopted EPA's MCLs for contaminants in public drinking water as allowable levels for the same contaminants in the quality standard regulations for bottled water. However, in some cases, FDA standards for bottled water differ from EPA standards for public drinking water. Lead is an example. In 1991, EPA adopted a requirement that public water systems treat their water to reduce lead when lead levels consistently exceed 15 parts per billion (ppb). The 15 ppb level took into account the fact that lead appears in public drinking water from corrosion of public water distribution systems and residential plumbing. However, leaching of lead from distribution systems is not a factor for bottled water and, based on its survey data, FDA concluded that bottlers can readily produce bottled water products with lead levels below 5 ppb. In 1994, FDA adopted an allowable level for lead at 5 ppb as a bottled water quality standard regulation. This action was consistent with FDA's goal of reducing consumers' exposure to lead in drinking water to the extent practicable.

Recent Regulatory Activities

In recent years, FDA has promulgated a number of quality standard regulations for bottled water in response to EPA regulatory activity. In March 2001, FDA adopted EPA's MCLs and maximum residual disinfectant levels (MRDL) for four disinfection byproducts (bromate, chlorite, haloacetic acids and total trihalomethanes) and for three disinfectants (chloramine, chlorine and chlorine dioxide), respectively, as allowable levels in its standard of quality regulations for bottled water, with the same effective date as that for EPA's regulations for the same contaminants in public drinking water.

In March 2003, FDA issued a final rule that amended its quality standard for bottled water by adopting EPA's MCL for uranium public drinking water as the allowable level for the same contaminant in bottled water.

In June 2005, FDA issued a final rule that amended its bottled water quality standard regulations by revising the existing allowable level for the contaminant arsenic. The revised allowable level for arsenic in bottled water is the same as EPA's MCL for arsenic in public drinking water.

This year, on May 29, 2009, FDA published a final rule in the Federal Register (74 FR 25664), to require that bottled water manufacturers test source water for total coliform, and to require, if any coliform organisms are detected, that bottled water manufacturers determine whether any of

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

Bill Osmunson, DDS, MPH
President, Washington Action for Safe Water
1418 112th Ave. NE
Bellevue, WA 98004

6/30/2010
In Reply refer to:
FOI# 2010-4601

Dear Requester:

This is in response to your request for record(s) from the Food and Drug Administration pursuant to the Freedom of Information Act regarding:

ITEM 3 - RECORDS RE: CONGRESSIONAL APPROVAL FOR FDA TO RELINQUISH DRUG REGULATORY APPROVAL FOR FLOURIDE IN DRINKING WATER

ITEM 4 - RECORDS RE: CONGRESSIONAL APPROVAL FOR EPA TO ASSUME JURISDICTION AS RELATED TO PUBLIC WATER SYSTEMS

ITEM 7 – RECORDS RE: CONGRESSIONAL AUTHORITY WHICH EXEMPTS DRUGS WHEN COMBINED WITH PUBLIC WATER FROM NDA REGULATORY PROCESS

A search of our system for the requested record(s) was conducted and no records were located. Therefore, we have no responsive records.

Please note - Some of the information you have requested (i.e. Legislative History re: Safe Water Drinking Act, and subsequent Amendments, are publically available; most likely through the Library of Congress.) As for Regulatory authority, please reference the Code of Federal Regulations (CFR) as they relate to the Safe Water Drinking Act. Last, with regard to MOU 225-79-2001, please see: www.FDA.gov for more information.

While we believe that an adequate search of appropriate files was conducted for the records requested, you have the right to appeal this finding that no records exist. Your appeal should be mailed within 30days from the date of this letter, to the Deputy Assistant Secretary for Public Affairs (Media), Room17A-46, 5600 Fishers Lane, Rockville, Maryland 20857. Clearly mark both the envelope and your letter - Freedom of Information Act Appeal.

Reproduction=$0.00Search=$46.00 Review=$0.00 Fiche=$0.00 Other=$0.00 **Total=$00.00**

The above total may not reflect final charges for this request, and you may receive responses from other parts of the Agency. Please do not send payment unless you receive an invoice.

All communications concerning this request should be identified with the reference number above and addressed as follows:

Food and Drug Administration
Freedom of Information Staff, HFI-35
5600 Fishers Lane (Room 6-30)
Rockville, MD 20857

Sincerely Yours,

Erik Henrikson
Office of Legislation

FYI only Enclosures:

- MOU 225-79-2001
- Statement of Joshua M. Sharfstein, M.D., Principle Deputy Commissioner of Food and Drugs re: Regulation of Bottled Water

the coliform organisms are Escherichia coli (E. coli), an indicator of fecal contamination. FDA's final rule also amends its bottled water regulations to require, if any coliform organisms are detected in finished bottled water products, that bottled water manufacturers determine whether any of the coliform organisms are E. coli.

Bottled water containing E. coli will be considered adulterated, and source water containing E. coli will not be considered to be of a safe, sanitary quality and will be prohibited from use in the production of bottled water. FDA is also requiring that, before a bottler can use source water from a source that has tested positive for E. coli, the bottler must take appropriate measures to rectify or eliminate the cause of E. coli contamination of that source, and that the bottler must keep records of such actions. Existing regulatory provisions require bottled water manufacturers to keep records of new testing required by this rule. The rule is effective on December 1 of this year.

ISSUES REGARDING FDA'S REGULATION OF BOTTLED WATER

General Accountability Office (GAO) Report

FDA has worked with GAO to provide information and assist with their investigation into bottled water regulation, and we have provided responses to their draft report. FDA is aware that the forthcoming GAO report highlights a number of challenges that the Agency faces in regulating bottled water.

While FDA has not seen the final version of the report, we understand that key concerns include that FDA currently does not have the ability to require the submission to the Agency of results from the testing conducted by and on behalf of bottled water manufacturers, and that FDA does not have specific authority to mandate the use of certified laboratories. These concerns are at least partially addressed by recent and pending legislation, as we discuss later below.

While GAO found FDA's standard of quality regulations generally equivalent to EPA regulations, it noted that FDA has not yet set a standard for di (2-ethylhexyl)phthalate (DEHP). GAO also found that FDA labeling regulations for bottled water provided for less information about the sources and quality of water than that required by EPA for municipal systems. On these two issues, we understand that GAO will recommend that the Secretary of HHS direct the Commissioner of FDA to:

- Issue a standard of quality regulation for DEHP or publish in the *Federal Register* the Agency's reasons for not doing so within 180 days of the conclusion of its task force study on the issue.
- Implement FDA's findings on methods that are feasible for conveying information about bottled water to customers, such as, at a minimum, requiring that companies provide on the label contact information directing customers how to obtain comprehensive information. Should FDA determine it lacks the necessary authority to implement its findings, it should seek legislation to obtain such authority.

DEHP

In the case of DEHP, FDA proposed in a 1993 *Federal Register* notice to adopt EPA's maximum contaminant level for this chemical in tap water as the allowable level in the bottled water quality standard regulations. A comment to this proposal pointed out that this chemical is permitted under the FD&C Act for use in certain types of food containers and closures. The comment raised the concern that lawful uses might result in levels of DEHP that would exceed the allowable level. Therefore, FDA's final rule published on March 26, 1996, stated that the Agency was deferring final action on the proposed allowable level for DEHP in bottled water. FDA agrees with GAO that it should make a decision regarding establishing a level for DEHP in bottled water. At this time, therefore, FDA has decided to move forward on making such a decision and has begun the decision making process.

Bottled Water Feasibility Study on Additional Disclosures to Consumers

Under the Safe Drinking Water Act Amendments of 1996, section 114(b), FDA was required to publish for notice and comment a study on the feasibility of appropriate methods of informing consumers about the contents of bottled water. FDA published a notice requesting comments on this issue in November 1997 and a draft feasibility study in February 2000. Based on these comments, FDA published a final study report on August 25, 2000 (65 *FR* 51833). The final study report evaluates information received from the comments and identifies appropriate and feasible methods for conveying information about the contents of bottled water to consumers. FDA believes it is feasible for bottled water manufacturers to provide consumers with additional information on bottled water comparable to the data provided by municipal water systems. However, the FD&C Act does not provide FDA with the authority to require bottled water manufactures to disclose such information.

Food Safety Enhancement Act (FSEA)

FDA believes that the legislation currently being developed by the Energy and Commerce Committee takes some positive steps in providing additional authority that will help to fill some of the gaps identified by GAO. Specifically, section 102 provides for food safety plans, hazard analyses and preventative controls that will complement FDA's cGMPs for bottled water facilities. For foreign-produced bottled water, FSEA requires importers to register with FDA and to comply with good importer practices, and gives FDA the authority to require certification as a condition of importation, in certain instances.

FSEA also provides FDA with the authority to establish science-based performance standards in section 103, routine access to records (section 106), and stronger criminal and civil penalties for violations of the FD&C Act (sections 134 and 135).

Finally, we note that upon implementation of the Reportable Food Registry provisions of the Food and Drug Administration Amendments Act of 2007 (PL 110-85), which FDA anticipates in early fall, bottlers will be required to report the results of tests showing that products in commerce pose a threat of serious adverse health consequences or death.

CONCLUSION

FDA regulates bottled water as a food under the FD&C Act and is responsible for ensuring that bottled water is safe and truthfully labeled. Specific FDA regulations for bottled water cover cGMPs for bottled water production and standards of identity and quality. Recent regulatory activity includes adoption of maximum allowable levels for critical contaminants, including certain disinfectants and disinfection byproducts, uranium, arsenic, and the adoption of testing and remediation requirements for the prevention of *E.coli* contamination.

FDA will carefully consider the conclusions of the GAO report and factor their findings into our future regulatory decisions. We will also continue to work with the Committee in your efforts to craft a bill that enhances food safety.

Thank you for the opportunity to testify.

APPENDIX

Table 1. Various types of bottled water.

TYPE	DEFINITION
Artesian Water	Water from a well tapping a confined aquifer in which the water level stands at some height above the top of the aquifer.
Mineral Water	Water containing not less than 250 ppm total dissolved solids that originates from a geologically and physically protected underground water source. Mineral water is characterized by constant levels and relative proportions of minerals and trace elements at the source. No minerals may be added to mineral water.
Purified Water	Water that is produced by distillation, deionization, reverse osmosis or other suitable processes and that meets the definition of "purified water" in the U.S. Pharmacopeia, 23d Revision, Jan. 1, 1995. As appropriate, also may be called "demineralized water," "deionized water," "distilled water," and "reverse osmosis water."
Sparkling Bottled Water	Water that, after treatment and possible replacement of carbon dioxide, contains the same amount of carbon dioxide that it had at emergence from the source.
Spring Water	Water derived from an underground formation from which water flows naturally to the surface of the earth at an identified location. Spring water may be collected at the spring or through a bore hole tapping the underground formation feeding the spring, but there are additional requirements for use of a bore hole.

(For complete regulatory definitions, see 21 CFR 165.110(a)(2).)

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MOU 225-79-2001

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:

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

B. That the scope of the additives problem in terms of the health significance of these contaminants in drinking water is not fully known;

C. 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;

D. 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;

E. 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;

F. 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;

G. 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,

H. 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:

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

B. 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 Section 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 reasonable 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 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 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 pre-manufacturing 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 substance 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.

Approved and Accepted
for the Environmental Protection Agency

Signed by: Douglas P. Costle
Administrator
Environmental Protection Agency

Date: June 12, 1979

Approved and Accepted
for the Food and Drug Administration

Signed by: Donald Kennedy
Administrator
Food and Drug Administration

Date: June 22, 1979

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