Zammit, President/CEO. Application Type: QI Change.

Dated: January 7, 2011.
Karen V. Gregory, Secretary.

[Federal Register Document]

BILLING CODE 6730-01-P

---

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Reissuance

Notice is hereby given that the following Ocean Transportation Intermediary licenses have been reissued by the Federal Maritime Commission pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. Chapter 409) and the regulations of the Commission pertaining to the licensing of Ocean Transportation Intermediaries, 46 CFR part 515.

<table>
<thead>
<tr>
<th>License No.</th>
<th>Name/address</th>
<th>Date reissued</th>
</tr>
</thead>
<tbody>
<tr>
<td>018429F</td>
<td>AB Shipping, Inc., 5428 El Monte Avenue, Temple City, CA 91780</td>
<td>November 15, 2010.</td>
</tr>
<tr>
<td>018525N</td>
<td>Valu Freight Consolidators, Inc., 1325 NW 21st Street, Miami, FL 33142</td>
<td>November 19, 2010.</td>
</tr>
<tr>
<td>020258NF</td>
<td>Sistemas Aereos LLC, 11027 NW 122nd Street, Medley, FL 33178</td>
<td>November 19, 2010.</td>
</tr>
<tr>
<td>020264N</td>
<td>Empire Shipping Co., Inc., 100 East Peddie Street, Newark, NJ 07114</td>
<td>November 6, 2010.</td>
</tr>
<tr>
<td>021534N</td>
<td>Martinez Cargo Express, Corp., 8026 Sunport Drive, Units 301–302, Orlando, FL 32809</td>
<td>November 19, 2010.</td>
</tr>
<tr>
<td>021694N</td>
<td>Wielosky Logistics, Inc., 14515 East Don Julian Road, City of Industry, CA 91746</td>
<td>November 19, 2010.</td>
</tr>
</tbody>
</table>

---

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board’s Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than January 28, 2011.

A. Federal Reserve Bank of Atlanta (Clifford Stanford, Vice President) 1000 Peachtree Street, N.E., Atlanta, Georgia 30309:

1. SG–BBC, LLC, and The Stephens Group, LLC, both of Little Rock, Arkansas; to acquire voting shares of Brand Group Holdings, Inc., and thereby indirectly acquire voting shares of The Brand Banking Company, both of Lawrenceville, Georgia.


Robert deV. Frierson, Deputy Secretary of the Board.

[FR Doc. 2010–575 Filed 1–12–11; 8:45 am]

BILLING CODE 6730-01-P

---

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Proposed HHS Recommendation for Fluoride Concentration in Drinking Water for Prevention of Dental Caries

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.
SUMMARY: The Department of Health and Human Services (HHS) seeks public comment on proposed new guidance which will update and replace the 1962 U.S. Public Health Service Drinking Water Standards related to recommendations for fluoride concentrations in drinking water. The U.S. Public Health Service recommendations for optimal fluoride concentrations were based on ambient air temperature of geographic areas and ranged from 0.7–1.2 mg/L.

HHS proposes that community water systems adjust the amount of fluoride to 0.7 mg/L to achieve an optimal fluoride level. For the purpose of this guidance, the optimal concentration of fluoride in drinking water is that concentration that provides the best balance of protection from dental caries while limiting the risk of dental fluorosis. Community water fluoridation is the adjusting and monitoring of fluoride in drinking water to reach the optimal concentration (Truman BI, et al, 2002).

This updated guidance is intended to apply to community water systems that are currently fluoridating or will initiate fluoridation. This guidance is based on several considerations that include:

- Scientific evidence related to effectiveness of water fluoridation on caries prevention and control across all age groups.
- Fluoride in drinking water as one of several available fluoride sources.
- Trends in the prevalence and severity of dental fluorosis.
- Current evidence on fluid intake in children across various ambient air temperatures.

DATES: To receive consideration, comments on the proposed recommendations for fluoride concentration in drinking water for the prevention of dental caries should be received no later than February 14, 2011.

ADDRESSES: Comments are preferred electronically and may be addressed to CWFcomments@cdc.gov. Written responses should be addressed to the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, CWF Comments, Division of Oral Health, National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), 4770 Buford Highway, NE, MS F–10, Atlanta, GA 30341–3717.

SUPPLEMENTARY INFORMATION: The U.S. Public Health Service has provided recommendations regarding optimal fluoride concentrations in drinking water from community water systems (CWS)2 for the prevention of dental caries (US DH/EW, 1962). HHS proposes to update and replace these recommendations because of new data that address changes in the prevalence of dental fluorosis, fluid intake among children, and the contribution of fluoride in drinking water to total fluoride exposure in the United States.

As of December 31, 2008, the Centers for Disease Control and Prevention (CDC) estimated that 16,977 community water systems provided fluoridated water to 196 million people. 95% of the population receiving fluoridated water was served by community water systems that added fluoride to water, or purchased water with added fluoride from other systems. The remaining 5% were served by systems with naturally occurring fluoride at or above the recommended level. More statistics about water fluoridation in the United States are available at http://www.cdc.gov/fluoridation/statistics/2008stats.htm. Guidance for systems with naturally occurring fluoride levels above the recommended level are beyond the scope of this document.

Systems that have fluoride levels greater than the national primary (4.0 mg/L) or secondary (2.0 mg/L) drinking water standards established by EPA can find more information at the following EPA Web site: http://water.epa.gov/drink/contaminants/basicinformation/fluoride.cfm. CDC’s Recommendations for Fluoride Use (CDC, 2001b), available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5014a1.htm, provides guidance on community water fluoridation and use of other fluoride-containing products.

RECOMMENDATION
HHS proposes that community water systems adjust their fluoride content to 0.7 mg/L [parts per million (ppm)].

Rationale
Importance of community water fluoridation:
Community water fluoridation is a major factor responsible for the decline of the prevalence and severity of dental caries (tooth decay) during the second half of the 20th century. From the early 1970’s to the present, the prevalence of dental caries in at least one permanent tooth (excluding third molars) among adolescents, aged 12–17 years,2 has decreased from 90% to 60% and the average number of teeth affected by dental caries (i.e., decayed, missing and filled) from 6.2 to 2.6 (Kelly JE, 1975, Dye B, et al, 2007). Adults have also benefited from community water fluoridation. Among adults, aged 35–44 years,4 the average number of affected teeth decreased from 18 in the early 1960’s to 10 among adults, aged 35–49 years, in 1999–2004 (Kelly JE, et al, 1967; Dye B, et al, 2007). Although there have been notable declines in tooth decay, it remains one of the most common chronic diseases of childhood (USDHHS, 2000; Newacheck PW et al, 2000). Effective population-based interventions to prevent and control dental caries, such as community water fluoridation, are still needed (CDC, 2001a).

Systematic reviews of the scientific evidence related to fluoride have concluded that community water fluoridation is effective in decreasing dental caries prevalence and severity (McDonagh MS, et al, 2000a, McDonagh MS, et al, 2000b, Truman BI, et al, 2002, Griffin SO, et al, 2007). Effects included significant increases in the proportion of children who were caries-free and significant reductions in the number of teeth or tooth surfaces with caries in both children and adults (McDonagh MS, et al, 2000b, Griffin SO, et al, 2007). When analyses were limited to studies 3  There were slight differences in the age groups used in both surveys. The 1971–1974 survey reported on adolescents aged 12–17 years (Kelly JE, 1975) while the 1999–2004 survey reported on adolescents and youths aged 12–19 years (Dye B, et al, 2007). Because the prevalence of dental caries increases with age, the estimates for 12–17 year olds in the most recent survey (1999–2004) should be slightly lower than those published for 12–19 year olds (Dye B, et al, 2007).

There were slight differences in the age groups used in both surveys. The 1962 survey reported on adults aged 35–44 years (Kelly JE et al 1967) while the 1999–2004 survey reported on adults aged 35–49 years (Dye B, et al, 2007).

1 Community water fluoridation of public drinking water systems has been demonstrated to be effective in reducing caries and producing cost savings from a societal perspective. (Truman B et al, 2002). If local goals and resources permit, the use of this intervention should be continued, initiated, or increased (CDC 2001).

4 For purposes of this guidance, a water system is considered a community water system if so designated by the State drinking water administrator in accordance with the regulatory requirements of the U.S. Environmental Protection Agency. In general, public water systems provide water for human consumption through pipes or other constructed conveyances to at least 15 service connections or serve an average of at least 25 people for at least 60 days a year. A community water system is a public water system that supplies water to the same population year-round, http://water.epa.gov/infrastructure/drinkingwater/pres/factoids.cfm.

3 For purposes of this guidance, a water system is considered a community water system if so designated by the State drinking water administrator in accordance with the regulatory requirements of the U.S. Environmental Protection Agency. In general, public water systems provide water for human consumption through pipes or other constructed conveyances to at least 15 service connections or serve an average of at least 25 people for at least 60 days a year. A community water system is a public water system that supplies water to the same population year-round, http://water.epa.gov/infrastructure/drinkingwater/pres/factoids.cfm.
conducted after the introduction of other sources of fluoride, especially fluoride toothpaste, beneficial effects across the lifespan from community water fluoridation were still apparent (McDonagh MS, et al, 2000b; Griffin SO, et al, 2007).

Fluoride works primarily to prevent dental caries through topical remineralization of tooth surfaces when small amounts of fluoride, specifically in saliva and accumulated plaque, are present frequently in the mouth (Featherstone JDB, 1999). Consuming fluoridated water and beverages and foods prepared or processed with fluoridated water routinely introduces a low concentration of fluoride into the mouth. Although other fluoride-containing products are available and contribute to the prevention and control of dental caries, community water fluoridation has been identified as the most cost-effective method of delivering fluoride to all members of the community regardless of age, educational attainment, or income level (CDC, 1999; Burt BA, 1989). Studies continue to find that community water fluoridation is cost-saving (Truman B, et al, 2002).

Trends in Availability of Fluoride Sources

Community water fluoridation and fluoride toothpaste are the most common sources of non-dietary fluoride in the United States (CDC, 2001b). Community water fluoridation began in 1945, reaching almost 50% of the U.S. population by 1975 and 64% by 2008, http://www.cdc.gov/fluoridation/statistics/2008stats.htm; http://www.cdc.gov/fluoridation/pdf/statistics/1975.pdf. Toothpaste containing fluoride was first marketed in the United States in 1955 (USDHEW, 1980) and by the 1990’s accounted for more than 90 percent of the toothpaste market (Burt BA and Eklund SA, 2005). Other products that provide fluoride now include mouthrinses, fluoride supplements, and professionally applied fluoride compounds. More detailed explanations of these products are published elsewhere (CDC, 2001b) (ADA, 2006) (USDHHS, 2010). More information on all sources of fluoride and their relative contribution to total fluoride exposure in the United States is presented in a report by EPA (US EPA 2010a).

Dental Fluorosis

Fluoride ingestion while teeth are developing can result in a range of visually detectable changes in the tooth enamel (Aoba T and Fejerskov O, 2002). Changes range from barely visible lacy white markings in milder cases to pitting of the teeth in the rare, severe form. The period of possible risk for fluorosis in the permanent teeth, excluding the third molars, extends from about birth through 8 years of age when the preeruptive maturation of tooth enamel is complete (CDC, 2001b; Massler M and Schour I, 1958). When communities first began adding fluoride to their public water systems in 1945, drinking water and foods and beverages prepared with fluoridated water were the primary sources of fluoride for most children (McClure FJ, 1943). Since the 1940’s, other sources of ingested fluoride, such as fluoride toothpaste (if swallowed) and fluoride supplements, have become available. Fluoride intake from these products, in addition to water and other beverages and infant formula prepared with fluoridated water, have been associated with increased risk of dental fluorosis (Levy SL, et al, 2010; Wong MCM, et al, 2010; Osuji OO et al, 1988; Pendry DS et al, 1994; Pendry DS and Katz RV 1989, Pendry DS, 1995). Both the 1962 USPHS recommendations and the current proposal for fluoride concentrations in community drinking water were set to achieve a reduction in dental caries while minimizing the risk of dental fluorosis.

Results of two national surveys indicate that the prevalence of dental fluorosis has increased since the 1980’s, but mostly in the very mild or mild forms. The most recent data on prevalence of dental fluorosis come from the National Health and Nutrition Examination Survey (NHANES), 1999–2004, NHANES assessed the prevalence and severity of dental fluorosis among persons, aged 6 to 49 years. Twenty-three percent had dental fluorosis of which the vast majority was very mild or mild. Approximately 2% of persons had moderate dental fluorosis, and less than 1% had severe. Prevalence was higher among younger persons and ranged from 41% among adolescents aged 12–15 years to 9% among adults, aged 40–49 years. The higher prevalence of dental fluorosis in the younger persons probably reflects the increase in fluoride exposures across the U.S. population through community water fluoridation and increased use of fluoride toothpaste.

The prevalence and severity of dental fluorosis among 12–15 year olds in 1999–2004 were compared to estimates from the Oral Health of United States Children Survey, 1986–87, which was the first national survey to include measures of dental fluorosis. Although these two national surveys differed in sampling and representation (schoolchildren versus household), findings support the hypothesis that there has been an increase in dental fluorosis that was very mild or greater between the two surveys. In 1986–87 and 1999–2004 the prevalence of dental fluorosis was 23% and 41%, respectively, among adolescents aged 12 to 15. (Beltrán-Aguilar ED, et al, 2010a). Similarly, the prevalence of very mild fluorosis (17.2% and 28.3%), mild fluorosis (4.1% and 8.6%) and moderate and severe fluorosis combined (1.3% and 3.6%) have increased. The estimates for severe fluorosis for adolescents in both surveys were statistically unreliable because of too few cases in the samples.

More information on fluoride concentrations in drinking water and the impact of severe dental fluorosis in children is presented in a report by EPA (US EPA 2010b).

Relationship between dental caries and fluorosis at varying water fluoridation concentrations:

The 1986–87 Oral Health of United States Children Survey is the only national survey that measured the child’s water fluoride exposure and can link that exposure to measures of caries and fluorosis (U.S. DHHS, 1989). An additional analysis of data from this survey examined the relationship between dental caries and fluorosis at varying water fluoride concentrations for children aged 6 to 17 years (Heller KE, et al, 1997). Findings indicate that there was a gradual decline in dental caries as fluoride content in water increased from negligible to 0.7 mg/L. Reductions plateaued at concentrations from 0.7 to 1.2 mg/L. In contrast, the percentage of children with at least very mild dental fluorosis increased with increasing fluoride concentrations in water. The published report did not report standard errors.

In Hong Kong a small change of about 0.2 mg/L in the mean fluoride concentration in drinking water in 1978 was associated with a detectable reduction in fluorosis prevalence by the
mid 1980’s \(^7\) (Evans R.W, Stamm JW., 1991). Across all age groups more than 90% of fluorosis cases were very mild or mild. (Evans R.W, Stamm JW., 1991). The study did not include measures of fluoride intake. Concurrently, dental caries prevalence did not increase. (Lo ECM et al., 1990). Although not fully generalizable to the current U.S. context, these findings, along with those from the 1986–87 survey of U.S. schoolchildren, suggest that risk of fluorosis can be reduced and caries prevention maintained toward the lower end (i.e., 0.7 mg/L) of the 1962 USPHS recommendations for fluoride concentrations for community water systems.

Relationship of fluid intake and ambient temperature among children and adolescents in the United States:

The 1962 USPHS recommendations stated that community drinking water should contain 0.7–1.2 mg/L [ppm] fluoride, depending on the ambient air temperature of the area. These temperature-related guidelines were based on studies conducted in two communities in California in the early 1950’s. Findings indicated that a lower fluoride concentration was appropriate for communities in warmer climates because children drank more tap water on warm days (Galagan DJ, 1953; Galagan DJ and Vermillion JR, 1957; Galagan DJ et al, 1957). Social and environmental changes, including increased use of air conditioning and more sedentary lifestyles, have occurred since the 1950’s, and thus, the assumption that children living in warmer regions drink more tap water than children in cooler regions may no longer be valid.

Studies conducted since 2001 suggest that fluid intake in children does not increase with increases in ambient air temperature (Sohn W, et al, 2001; Beltran-Aguilar ED, et al, 2010b). One study conducted among children using nationally representative data from 1988 to 1994 did not find an association between fluid intake and ambient air temperature (Sohn W, et al, 2001). A similar study using nationally representative data from 1999 to 2004 also found no association between fluid intake and ambient temperature among children or adolescents (Beltran-Aguilar ED, et al, 2010b). These recent findings demonstrating a lack of an association between fluid intake among children and adolescents and ambient temperature support use of a single target concentration for community water fluoridation in all temperature zones of the United States.

**Conclusions**

HHS recommends an optimal fluoride concentration of 0.7 mg/L for community water systems based on the following information:

- Community water fluoridation is the most cost-effective method of delivering fluoride for the prevention of tooth decay;
- In addition to drinking water, other sources of fluoride exposure have contributed to the prevention of dental caries and an increase in dental fluorosis prevalence;
- Significant caries preventive benefits can be achieved and risk of fluorosis reduced at 0.7 mg/L, the lowest concentration in the range of the USPHS recommendation.

**Recent data do not show a convincing relationship between fluid intake and ambient air temperature. Thus, these findings support the recommendation for different concentrations for different temperature zones.**

**Surveillance Activities**

CDC and the National Institute of Dental and Craniofacial Research (NIDCR), in coordination with other Federal agencies, will enhance surveillance of dental caries, dental fluorosis, and fluoride intake with a focus on younger populations at higher risk of fluorosis to obtain the best available and most current information to support effective efforts to improve oral health.

**Process**

The U.S. Department of Health and Human Services (HHS) convened a Federal inter-departmental, inter-agency panel of scientists (Appendix A) to review scientific evidence related to the 1962 USPHS Drinking Water Standards related to recommendations for fluoride concentration in drinking water in the United States and to update these proposed recommendations. Panelists included representatives from the Centers for Disease Control and Prevention, the National Institutes of Health, the Food and Drug Administration, the Agency for Healthcare Research and Quality, the Office of the Assistant Secretary for Health, the U.S. Environmental Protection Agency, and the U.S. Department of Agriculture. The panelists evaluated existing recommendations for fluoride in drinking water, systematic reviews of the risks and benefits from fluoride in drinking water, the epidemiology of dental caries and fluorosis in the U.S., and current data on fluid intake in children, aged 0 to 10 years, across temperature gradients in the U.S. Conclusions were reached and are summarized along with their rationale in this proposed guidance document. This guidance will be advisory, not regulatory, in nature. Guidance will be submitted to the Federal Register and will undergo public and stakeholder comment for 30 days, after which HHS will review comments and consider changes.

Dated: January 7, 2011.

Kathleen Sebelius, Secretary.

**References**


---

\(^7\) Fluorosis prevalence ranged from 64% (SE = 4.1) to 47% (SE = 4.5) based on the upper right central incisor only.


DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Biodefense Science Board

AGENCY: Department of Health and Human Services, Office of the Secretary.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services is hereby giving notice that the National Biodefense Science Board (NBSB) will be holding a public meeting. The meeting is open to the public.

DATES: The NBSB will hold a public meeting on January 25, 2011 from 1:15 p.m. to 3 p.m. ET. The agenda is subject to change as priorities dictate.

ADDRESSES: Department of Health and Human Services; Hubert H. Humphrey Building, Room 800; 200 Independence Avenue, SW., Washington, DC 20201.

To attend by teleconference, call 1–866–395–4129, pass-code “ASPR.” Please call 15 minutes prior to the beginning of the conference call to facilitate attendance.

Any member of the public providing oral comments at the meeting must sign in at the registration desk and provide his/her name, address, and affiliation. All written comments must be received prior to January 18, 2011 and should be sent by e-mail to NBSB@HHS.GOV with “NBSB Public Comment” as the subject line. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should e-mail NBSB@HHS.GOV.

Dated: January 7, 2011.

Nicolette Lurie,
Assistant Secretary for Preparedness and Response.

[FR Doc. 2011–684 Filed 1–12–11; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Toxicology Program (NTP); NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM); Federal Agency Responses to Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) Recommendations on Two Nonradioactive Versions of the Murine Local Lymph Node Assay (LLNA) for Assessing Allergic Contact Dermatitis (ACD) Hazard Potential of Chemicals and Products, and Expanded Uses of the LLNA for Pesticide Formulations and Other Products; Notice of Availability

AGENCY: National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), HHS.

ACTION: Notice of Availability.

SUMMARY: U.S. Federal agency responses to ICCVAM test method recommendations on two nonradioactive versions of the LLNA for assessing the ACD hazard potential of chemicals and products and for expanded uses of the LLNA for pesticide formulations and other products are now available on the NICEATM–ICCVAM Web site at http://iccvam.niehs.nih.gov/methods/immunotox/llna.htm. ICCVAM recommended the nonradioactive LLNA: 5-bromo-2-deoxyuridine–enzyme-linked immunosorbent assay

Availability of Materials: The meeting agenda and materials will be posted on the NBSB Web site at http://www.phe.gov/Preparedness/legal/boards/nbsb/Pages/default.aspx prior to the meeting.

Procedures for Providing Public Input: Any member of the public providing oral comments at the meeting must sign in at the registration desk and provide his/her name, address, and affiliation. All written comments must be received prior to January 18, 2011 and should be sent by e-mail to NBSB@HHS.GOV with “NBSB Public Comment” as the subject line. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should e-mail NBSB@HHS.GOV.

Dated: January 7, 2011.

Nicolette Lurie,
Assistant Secretary for Preparedness and Response.

[FR Doc. 2011–684 Filed 1–12–11; 8:45 am]