

have a significant economic impact on a substantial number of small entities as that term is defined in the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* The factual basis is found in the proposed rule and is not repeated here. No comments were received on the certification or the economic impacts of this action. As a result, no final regulatory flexibility analysis was prepared.

#### Paperwork Reduction Act

This final rule contains collection-of-information requirements subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA). These requirements have been approved by OMB (OMB No. 0625-0245; Expiration Date: 09/30/2011). Public reporting for this collection of information is estimated to be less than ten minutes per response, including the time for reviewing instructions and completing and reviewing the collection of information. All responses to this collection of information are voluntary, and will be provided confidentially to the extent allowed by law.

Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection of information subject to the Paperwork Reduction Act unless that collection displays a currently valid OMB Control Number.

#### List of Subjects in 19 CFR Part 360

Administrative practice and procedure, Business and industry, Imports, Reporting and recordkeeping requirements, Steel.

Dated: March 13, 2009.

Michelle O'Neill,

Acting Under Secretary for International Trade.

■ For reasons discussed in the preamble, 19 CFR part 360 is amended to read as follows:

#### PART 360—STEEL IMPORT MONITORING AND ANALYSIS SYSTEM

■ 1. The authority citation for part 360 continues to read as follows:

**Authority:** 13 U.S.C. 301(a) and 302.

■ 2. Section 360.105 is revised to read as follows:

##### § 360.105 Duration of the steel import licensing requirement.

The licensing program will be in effect through March 21, 2013, but may be extended upon review and notification in the **Federal Register** prior to this expiration date. Licenses

will be required on all subject imports entered during this period, even if the entry summary documents are not filed until after the expiration of this program. The licenses will be valid for 10 business days after the expiration of this program to allow for the final filing of required Customs documentation.

[FR Doc. E9-6013 Filed 3-16-09; 4:15 pm]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 172

[Docket No. FDA-2005-F-0505] (formerly Docket No. 2005F-0138)

#### Food Additives Permitted for Direct Addition to Food for Human Consumption; Silver Nitrate and Hydrogen Peroxide

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of an aqueous solution of silver nitrate and hydrogen peroxide as an antimicrobial agent in bottled water. This action is in response to a petition filed by Kareem I. Batarseh.

**DATES:** This final rule is effective March 18, 2009. Submit written or electronic objections and requests for a hearing by April 17, 2009. See section VIII of this document for information on the filing of objections. The Director of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications in 21 CFR 172.167 as of March 18, 2009.

**ADDRESSES:** You may submit written or electronic objections and requests for a hearing identified by Docket No. FDA-2005-F-0505 (formerly Docket No. 2005F-0138) by any of the following methods:

##### Electronic Submissions

Submit electronic objections in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

##### Written Submissions

Submit written objections in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA-

305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of objections, FDA is no longer accepting objections submitted to the agency by e-mail. FDA encourages you to continue to submit electronic objections by using the Federal eRulemaking Portal, as described in the *Electronic Submissions* portion of this paragraph.

**Instructions:** All submissions received must include the agency name and docket number for this rulemaking. All objections received will be posted without change to <http://www.regulations.gov>, including any personal information provided. For detailed instructions on submitting objections, see the "Objections" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

**Docket:** For access to the docket to read background documents or objections received, go to <http://www.regulations.gov> and insert the docket number(s), found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Mical E. Honigfort, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 301-436-1278.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In a notice published in the **Federal Register** of April 18, 2005 (70 FR 20145), FDA announced that a food additive petition (FAP 5A4759) had been filed by Kareem I. Batarseh, P.O. Box 8, College Park, MD 20741-0008. The petition proposed to amend the food additive regulations in part 172, *Food Additives Permitted for Direct Addition to Food for Human Consumption* (21 CFR part 172), to provide for the safe use of an aqueous solution of silver nitrate and hydrogen peroxide as an antimicrobial agent in bottled drinking water at a level not to exceed 17 micrograms per kilogram ( $\mu\text{g}/\text{kg}$ ) of silver and 23 milligrams per kilogram (mg/kg) of hydrogen peroxide in the treated bottled water.

##### II. Evaluation of Safety

Under the general safety standard in section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348), a food additive cannot be approved for a particular use unless a fair evaluation of the data available to

FDA establishes that the additive is safe for that use. FDA's food additive regulations (21 CFR 170.3(i)) define safe as "a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use."

To establish with reasonable certainty that a food additive is not harmful under its intended conditions of use, FDA considers the estimated human dietary intake of the additive, the additive's toxicological data, and other relevant information (such as published literature) available to the agency. FDA compares an individual's estimated daily intake (EDI) of the additive to an acceptable intake level established by toxicological data. The EDI is determined by projections based on the amount of the additive proposed for use in particular foods and on data regarding the amount consumed from all sources of the additive. The agency commonly uses the EDI for the 90th percentile consumer of a food additive as a measure of high chronic dietary intake.

FDA estimates the EDI of silver from the petitioned use in bottled water to be 26 micrograms per person per day ( $\mu\text{g}/\text{p}/\text{d}$ ) for the 90th percentile consumer aged 2 years or more (Ref. 1). Currently, silver is permitted as a component of an antimicrobial agent in water filters (the subject of effective food contact substance notification number 351 (Ref. 2)). The EDI from this filter use is 27  $\mu\text{g}/\text{p}/\text{d}$  for the 90th percentile consumer. The petitioner has proposed as a condition of safe use that the subject additive not be used in bottled water that has been or is intended to be filtered with a silver-containing water filter. Consequently, bottled water containing the subject additive will generally be consumed as a substitute for, rather than in addition to, bottled water that has been filtered with a silver-containing filter. Thus, the use of the subject additive in bottled water will not increase consumer exposure to silver. Because there is no increase in the intake of silver beyond a level that has already been established as safe, FDA has no concerns regarding the petitioned use of silver as a component of this additive.

Regarding exposure to nitrate from use of the subject additive, FDA estimates that the maximum level of nitrate in bottled drinking water treated with the subject additive would result in a worst-case intake of 15  $\mu\text{g}/\text{p}/\text{d}$  at the 90th percentile (Ref. 1), which is equivalent to 0.25 micrograms per kilogram body weight per day ( $\mu\text{g}/\text{kg}\text{-bw}/\text{d}$ ) in a 60 kg adult. FDA has no safety concerns because the intake of

nitrate in bottled drinking water treated with the subject additive is significantly lower than the chronic oral reference dose of 1,600  $\mu\text{g}/\text{kg}\text{-bw}/\text{d}$  for nitrate that was established by the Environmental Protection Agency (Ref. 3).

FDA also has no safety concerns regarding the use of hydrogen peroxide as a component of this additive as it will rapidly break down to water and oxygen after addition to the bottled water. Consequently, the dietary exposure to hydrogen peroxide from the petitioned use of the subject additive is essentially zero (Ref. 1).

### III. Conclusion

FDA reviewed data in the petition and other available relevant material to evaluate the safety of the use of a mixture of silver nitrate and hydrogen peroxide as an antimicrobial agent in bottled water. Based on this information, the agency concludes that the proposed use of the additive is safe and the additive will achieve its intended technical effect as an antimicrobial agent under the proposed conditions of use. Therefore, the regulations in part 172 should be amended as set forth in this document.

To ensure that food grade hydrogen peroxide is used in food, the additive must meet the specifications for hydrogen peroxide set forth in this regulation.

FDA notes that bottled water must meet the quality standards for bottled water in § 165.110(b)(2) through (b)(5) (21 CFR 165.110(b)(2) through (b)(5)), including the limits specified for total silver and nitrate, unless the water bears a label statement of substandard quality, as provided for under § 165.110(c) (21 CFR 165.110(c)). Furthermore, bottled water containing a substance at a level considered injurious to health under section 402(a)(1) of the act (21 U.S.C. 342(a)(1)) is deemed adulterated, regardless of whether or not the water bears a label statement of substandard quality, § 165.110(d) (21 CFR 165.110(d)).

### IV. Public Disclosure

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition will be made available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure

before making the documents available for inspection.

### V. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the notice of filing for FAP 5A4759. No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

### VI. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

### VII. Section 301(ll) of the Federal Food, Drug, and Cosmetic Act

FDA's review of this petition was limited to section 409 of the act. This final rule is not a statement regarding compliance with other sections of the act. For example, the Food and Drug Administration Amendments Act of 2007, which was signed into law on September 27, 2007, amended the act to, among other things, add section 301(ll) (21 U.S.C. 301(ll)). Section 301(ll) of the act prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the act (21 U.S.C. 355), a biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), or a drug or biological product for which substantial clinical investigations have been instituted and their existence has been made public, unless one of the exceptions in 21 U.S.C. 301(ll)(1) to (ll)(4) applies. In our review of this petition, FDA did not consider whether section 301(ll) or any of its exemptions apply to food containing this additive. Accordingly, this final rule should not be construed to be a statement that a food containing this additive, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll). Furthermore, this language is included in all food additive final rules and therefore should not be construed to be a statement of the likelihood that section 301(ll) applies.

### VIII. Objections

Any person who will be adversely affected by this regulation may file with the Division of Dockets Management (see **ADDRESSES**) written or electronic objections. Each objection shall be separately numbered, and each numbered objection shall specify with

particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents are to be submitted and are to be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

#### IX. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum from D. Doell, Division of Petition Review, CFSAN, FDA to M. Honigfort, Division of Petition Review, CFSAN, FDA, June 14, 2005.

2. FDA, Inventory of Effective Food Contact Substance (FCS) Notifications, Food Contact Substance Notification Number 351 (<http://www.cfsan.fda.gov/~dms/opa-fcn.html>).

3. Environmental Protection Agency, Integrated Risk Information System: Nitrate (CASRN 14797-55-8) (<http://www.epa.gov/ncea/iris/subst/0076.htm>). (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**).

#### List of Subjects in 21 CFR Part 172

Food additives, Incorporation by reference, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 172 is amended as follows:

#### PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

■ 1. The authority citation for 21 CFR part 172 continues to read as follows:

**Authority:** 21 U.S.C. 321, 341, 342, 348, 371, 379e.

■ 2. Section 172.167 is added to subpart B to read as follows:

##### § 172.167 Silver nitrate and hydrogen peroxide solution.

An aqueous solution containing a mixture of silver nitrate and hydrogen peroxide may be safely used in accordance with the following prescribed conditions:

(a) The additive is used as an antimicrobial agent in bottled water.

(b) Hydrogen peroxide meets the specifications of the “Food Chemicals Codex,” 6th ed. (2008), pp. 463 and 464, which is incorporated by reference. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address <http://www.usp.org>). Copies may be examined at the Center for Food Safety and Applied Nutrition’s Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2163, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(c) The amount of silver added will not exceed 17 micrograms per kilogram in the treated bottled water, and the amount of hydrogen peroxide will not exceed 23 milligrams per kilogram in the treated bottled water. Analyses for silver and hydrogen peroxide shall be conducted on samples of treated bottled water at the site of bottling, using samples of the water intended for treatment for the blank determination.

(d)(1) The amount of silver in the treated bottled water is determined using the method for silver designated in 21 CFR 165.110(b)(4)(iii)(G)(2)(i).

(2) The amount of hydrogen peroxide in the treated bottled water is determined using a Hydrogen Peroxide Test Kit from the HACH Co., or equivalent. The manual from the Hydrogen Peroxide Test Kit, Model HYP-1, Catalog Number 22917-00, 1991, is incorporated by reference. The Director of the Federal Register approves this incorporation by reference

in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies of the test kit manual from the HACH Co., P.O. Box 389, Loveland CO, 80359 (1-800-227-4224), Model HYP-1, Catalog Number 22917-00. Copies may be examined at the Center for Food Safety and Applied Nutrition’s Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2163, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(e) Substances generally recognized as safe in or on food may be used to stabilize the additive to ensure that the additive will perform its intended technical effect.

(f) The additive may not be added to bottled water that has been filtered or is intended to be filtered through a silver-containing water filter.

(g) Bottled water must meet the quality standards for bottled water in § 165.110(b)(2) through (b)(5) of this chapter, including the limits specified for total silver and nitrate, unless the water bears a label statement of substandard quality, as provided for under § 165.110(c) of this chapter.

Dated: March 12, 2009.

**Leslye M. Fraser,**

*Director, Office of Regulations and Policy,  
Center for Food Safety and Applied Nutrition.*  
[FR Doc. E9-5852 Filed 3-17-09; 8:45 am]

**BILLING CODE 4160-01-S**

#### OFFICE OF THE DIRECTOR OF NATIONAL INTELLIGENCE

##### 32 CFR Part 1702

#### Procedures Governing the Acceptance of Service of Process Upon the Office of the Director of National Intelligence and Its Employees in Their Official, Individual or Combined Official and Individual Capacities

**AGENCY:** Office of the Director of National Intelligence.

**ACTION:** Final rule.

**SUMMARY:** This final regulation governs the procedures the ODNI will follow for the acceptance of service of process upon the ODNI and its employees in their official, individual or combined official and individual capacities.

**DATES:** *Effective Date:* March 18, 2009.

**FOR FURTHER INFORMATION CONTACT:** Tricia Wellman, 703-275-2527.