DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0195]

Small Entity Compliance Guide: Bottled Water: Uranium; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Bottled Water: Uranium—Small Entity Compliance Guide'' for a direct final rule published in the **Federal Register** of March 3, 2003. This small entity compliance guide (SECG) is intended to set forth in plain language the requirements of the regulation and to help small businesses understand the regulation.

DATES: Submit written or electronic comments on the SECG at any time.

ADDRESSES: Submit written requests for single copies of the SECG to the Division of Plant and Dairy Food Safety (HFS–317), Office of Food Safety, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or fax your request to 301–436–2651. Send one self-addressed adhesive label to assist that office in processing your request.

Submit written comments on the SECG to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the SECG to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the SECG.

FOR FURTHER INFORMATION CONTACT: Paul South, Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1640.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 3, 2003 (68 FR 9873), FDA issued a direct final rule amending its bottled water quality standard regulations by establishing an allowable level for the contaminant uranium. FDA also retained the existing allowable levels for combined radium-226/-228, gross alpha particle radioactivity, and beta particle and photon radioactivity. On June 9, 2003, FDA confirmed the effective date of December 8, 2003, for the direct final rule (68 FR 34272).

FDA examined the economic implications of the direct final rule as required by the Regulatory Flexibility Act (5. U.S.C. 601–612) and determined that the rule would have a significant economic impact on a substantial number of small entities. In compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121), FDA is making available this SECG stating in plain language the legal requirements of the March 3, 2003, direct final rule set forth in 21 CFR part 165 concerning the contaminant uranium.

FDA is issuing this SECG as level 2 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115(c)(2)). The SECG represents the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The SECG and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.cfsan.fda.gov/guidance.html*.

Dated: April 24, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0196]

Small Entity Compliance Guide: Bottled Water: Arsenic; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Bottled Water: Arsenic—Small Entity Compliance Guide'' for a final rule published in the **Federal Register** of June 9, 2005. This small entity compliance guide (SECG) is intended to set forth in plain language the requirements of the regulation and to help small businesses understand the regulation.

DATES: Submit written or electronic comments on the SECG at any time.

ADDRESSES: Submit written requests for single copies of the SECG to the Division of Plant and Dairy Food Safety (HFS–317), Office of Food Safety, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or fax your request to 301–436–2651. Send one self-addressed adhesive label to assist that office in processing your request.

Submit written comments on the SECG to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the SECG to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the SECG.

FOR FURTHER INFORMATION CONTACT: Paul South, Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1640.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 9, 2005 (70 FR 33694), FDA issued a final rule amending its bottled water quality standard regulations by revising the existing allowable level for the contaminant arsenic. This final rule became effective on January 23, 2006.

FDA examined the economic implications of the final rule as required by the Regulatory Flexibility Act (5. U.S.C. 601–612) and determined that the rule would have a significant economic impact on a substantial number of small entities. In compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121), FDA is making available this SECG stating in plain language the legal requirements of the June 9, 2006, final rule set forth in 21 CFR part 165 concerning the contaminant arsenic.