DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration


Leslie Kux,
Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0316]

Small Entity Compliance Guide: bottled water: Quality Standard: Establishing an Allowable Level for di(2-ethylhexyl)phthalate; 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: Quality Standard: Establishing an Allowable Level for di(2-ethylhexyl)phthalate—Small Entity Compliance Guide.” The small entity compliance guide (SECG) is being issued for a final rule published in the Federal Register on October 19, 2011, and is intended to set forth in plain language the requirements of the regulation and to help small businesses understand the regulation.

DATES: Submit either electronic or written comments on Agency guidance at any time.

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

Submit electronic comments on the SECG to http://www.regulations.gov. 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.


SUPPLEMENTARY INFORMATION: I. Background

In the Federal Register of October 19, 2011 (76 FR 64810), FDA issued a final rule that amended its bottled water standard of quality regulations by establishing an allowable level for di(2-ethylhexyl)phthalate (DEHP). This final rule is effective April 16, 2012.

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 final rule will not 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 (Pub. L. 104–121), FDA is making available this SECG stating in plain language the requirements of the regulation.

FDA is issuing this SECG consistent with FDA’s good guidance practices regulation (21 CFR 10.115(c)(2)). This SECG represents the Agency’s current thinking on di(2-ethylhexyl)phthalate in bottled water. 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) either electronic or written comments regarding this SECG. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. 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 SECG at either http://www.fda.gov/RegulatoryInformation/Guidances/default.htm or http://www.regulations.gov. Always access an FDA guidance document by using FDA’s Web site listed previously to find the most current version of the guidance.


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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2011–0975]

National Maritime Security Advisory Committee; Meeting

AGENCY: Coast Guard, DHS.

ACTION: Notice of Partially Closed Federal Advisory Committee Meeting.

SUMMARY: The National Maritime Security Advisory Committee (NMSAC) will meet on May 15–16, 2012 in the Washington, DC metropolitan area to discuss various issues relating to national maritime security. The meeting will be partially closed to the public.

DATES: The Committee will meet in a closed session on Tuesday, May 15, 2012 from 9 a.m. to 11:30 a.m. and in open session on Tuesday, May 15, 2012 from 1 p.m. to 4:30 p.m. and Wednesday, May 16, 2012 from 9 a.m. to 12 p.m. This meeting may close early if all business is finished.

All written material and requests to make oral presentations should reach the Coast Guard on or before May 9, 2012.

ADDRESSES: The Committee will meet in closed session at National Maritime Intelligence Center and in open session at the American Bureau of Shipping, 1400 Key Blvd., Suite 800, Arlington, Virginia 22209. Seating is very limited; members of the public wishing to attend the open sessions should register with Mr. Ryan Owens, Alternate Designated Federal Official (ADFO) of NMSAC, telephone 202–372–1108 or ryan.f.owens@uscg.mil no later than May 9, 2012. Additionally, the open sessions of this meeting will be broadcasted via a Web-enabled interactive online format and teleconference.

To participate via teleconference, dial 866–717–0091; the pass code to join is 3038389. Additionally, if you would like to participate in this meeting via the online Web format, please log onto https://connect.hsin.gov/r11254182 and follow the online instructions to register for this meeting.

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact the person listed in the FOR FURTHER INFORMATION CONTACT section as soon as possible.

To facilitate public participation, we are inviting public comment on the issues to be considered by the committee as listed in the “Agenda” section below. You may submit written...