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 guidances 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. 5100, 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. 104–115), 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.


Leslie Kux,

Assistant Commissioner for Policy.

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. 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
comments no later than May 9, 2012 and identified by docket number [USCG–2011–0975] by using one of the following methods:

- Mail: Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. We encourage use of electronic submissions because security screening may delay delivery of mail.
- Fax: (202) 493–2251.
- Hand Delivery: Same as mail address above, between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal Holidays. The telephone number is 202–366–9329.
- Instructions: All submissions received must include the words “Department of Homeland Security” and docket number [USCG–2011–0975]. All submissions received will be posted without alteration at www.regulations.gov, including any personal information provided. You may review a Privacy Act notice regarding our public docket in the January 17, 2008 issue of the Federal Register (73 FR 3316).
- Docket: Any background information or presentations available prior to the meeting will be published in the docket. For access to the docket to read background documents or submissions received by the NMSAC, go to http://www.regulations.gov and use “USCG–2011–0975” as your search term.

Public comment period will be held during the open portion of the meetings on May 15, 2012, from 4:00 p.m. to 4:30 p.m., and May 16, 2012 from 11:30 a.m. to 12 p.m. Speakers are requested to limit their comments to 5 minutes. Please note that the public comment period will end following the last call for comments. Contact the person listed in the FOR FURTHER INFORMATION CONTACT section below to register as a speaker.

FOR FURTHER INFORMATION CONTACT: Mr. Ryan Owens, ADFO of NMSAC, 2100 2nd Street SW., Stop 7581, Washington, DC 20593–7581; telephone 202–372–1108 or email ryan.f.owens@uscg.mil. If you have any questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. App. (Pub. L. 92–463). NMSAC operates under the authority of 46 U.S.C. 70112. NMSAC provides advice, consults with, and makes recommendations to the Secretary of Homeland Security, via the Commandant of the Coast Guard, on matters relating to national maritime security.

Agenda of Meeting

Day 1

The agenda for the Committee meeting is as follows:

1. Classified Security Briefing for NMSAC members only. Closed to the public.

Basis for Closure. In accordance with Section 10(d) of the Federal Advisory Committee Act, it has been determined that this portion of the meeting requires closure as the disclosure of the information would not be in the public interest. There will be briefings from personnel from Coast Guard Intelligence Coordination Center regarding current domestic and international security threats to maritime commerce. Under 5 U.S.C. 552b(c)(1), this information is specifically authorized under criteria established by Executive Order 12968 to be kept secret in the interests of national defense or foreign policy. Accordingly, this portion of the meeting will be closed to the public.

2. Global Supply Chain Security Initiative. Per the SAFE Port Act (Pub. L. 109–347) the Coast Guard consults with the NMSAC on the Global Supply Chain Security Initiative. The Committee will receive an update and provide further guidance/recommendations on this initiative.

3. Transport Canada/USCG Regulatory Harmonization. The Committee will receive an update from Transport Canada and the USCG on efforts to harmonize Security Regulations across the Northern Border. The Committee will then provide recommendations on these efforts.

4. Detain On-Board Requirements. NMSAC will receive an update from the chair of the NMSAC working group and vote on recommendations concerning Coast Guard and U.S. Customs and Border Protection (CBP) field guidance pertaining to requirements for vessels to post or contract for guards while in U.S. ports.

5. Port Security Grant Program and Transportation Worker Identification Credential (TWIC) Readers. The NMSAC will receive an update and provide guidance on efforts to accommodate TWIC readers into the Port Grant Program as a result of the Completion of the TWIC Reader Pilot.

6. Public Comment Period. NMSAC will hear any other matters raised by the public. Please note that the public will have an opportunity to comment throughout the day on each topic as it is discussed.

Day 2

7. Maritime Domain Awareness and Information Sharing. The Committee will hold a follow up discussion from its last meeting to discuss the results of the Committee’s efforts to poll the maritime industry on what gaps still remain in information sharing between the industry and the Federal Government with a panel of DHS Information Sharing Executives.

8. Public comment period. NMSAC will hear any other matters raised by the public. Please note that the public will have an opportunity to comment throughout the day on each topic as it is discussed.


P.F. Thomas,
Captain, U.S. Coast Guard, Acting Director of Prevention Policy.

Agency Information Collection Activities: Form I–212; Extension of an Existing Information Collection; Comment Request

ACTION: 60-Day Notice of Information Collection Under Review; Form I–212, Application for Permission to Reapply for Admission into the United States after Deportation or Removal.

The Department of Homeland Security. U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. This information collection notice is published in the Federal Register to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for sixty days until July 2, 2012.

During this 60 day period, USCIS will be evaluating whether to revise the Form I–212. Should USCIS decide to revise Form I–212 we will advise the public when we publish the 30-day notice in the Federal Register in accordance with the Paperwork Reduction Act. The public will then