In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: April 23, 2012.

Steven Hanmer,

Reports Clearance Officer.

[FR Doc. 2012–10305 Filed 4–30–12; 8:45 am]

BILLING CODE 4184–22–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–P–0025]

Determination That GRIFULVIN V (Griseofulvin Microcrystalline) Tablets, 250 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that GRIFULVIN V (griseofulvin microcrystalline) tablets, 250 milligrams (mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for griseofulvin microcrystalline tablets, 250 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Nancy Hayes, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6244, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

GRIFULVIN V (griseofulvin microcrystalline) tablets, 250 mg, is the subject of ANDA 062279, held by OrthoNeutrogena, and approved on June 2, 1980. GRIFULVIN V is indicated for the treatment of certain ringworm infections (tinea corporis, tinea pedis, tinea cruris, tinea barbae, tinea capitis, and tinea unguium) when caused by a certain genera of fungi.

GRIFULVIN V (griseofulvin microcrystalline) tablets, 250 mg, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Arthur Y. Tsien of Olsson Frank Weeda Terman Bode Matz PC submitted a citizen petition on behalf of a client, dated January 7, 2011 (Docket No. FDA–2011–P–0025), under 21 CFR 10.30, requesting that the Agency determine whether GRIFULVIN V (griseofulvin microcrystalline) tablets, 250 mg, was withdrawn from sale for reasons of safety or effectiveness. After considering the citizen petition and reviewing Agency records, FDA has determined under § 314.161 that GRIFULVIN V (griseofulvin microcrystalline) tablets, 250 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that GRIFULVIN V (griseofulvin microcrystalline) tablets, 250 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of GRIFULVIN V (griseofulvin microcrystalline) tablets, 250 mg, from sale. We have also independently reviewed relevant literature and data for possible postmarketing adverse event reports. We have found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list GRIFULVIN V (griseofulvin microcrystalline) tablets, 250 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to GRIFULVIN V (griseofulvin microcrystalline) tablets, 250 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: April 26, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–10466 Filed 4–30–12; 8:45 am]

BILLING CODE 4160–01–P

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** of 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. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lauren Posnick Robin, Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1639.

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.

Dated: April 26, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–10465 Filed 4–30–12; 8:45 am]

BILLING CODE 4160–01–P

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