Kimberly S. Lane,

Deputy Director, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2012–29474 Filed 12–5–12; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

The Centers for Disease Control (CDC)/ Health Resources and Services Administration (HRSA) Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment Notice of Charter Renewal

This gives notice under the Federal Advisory Committee Act (Pub. L. 92–463) of October 6, 1972, that the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment, Department of Health and Human Services, has been renewed for a 2-year period through November 25, 2014.

Contact Person for More Information: Kevin Fenton, M.D., Ph.D., Designated Federal Officer, CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment, Department of Health and Human Services, CDC, 1600 Clifton Road, NE., Mailstop E07, Atlanta, Georgia 30333, telephone (404) 639–8000 or fax (404) 639–8600.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: November 29, 2012.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2012–29471 Filed 12–5–12; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Request for Nominations for Candidates To Serve on the National Public Health Surveillance and Biosurveillance Advisory Committee (NPHSBAC)

Correction: This notice was published in the **Federal Register** on November 1, 2012 Volume 77, Number 215, page 66620. This notice is to announce the extension of submission for potential nominees.

Nominations should be sent, in writing, and postmarked by December 21, 2012: Vernellia Johnson, Management and Program Analyst, Public Health Surveillance and Informatics Program Office, Centers for Disease Control and Prevention, Office of Surveillance, Epidemiology and Laboratory Services Century, 1600 Clifton Road NE., MS E–97, Atlanta, GA 30333 or via email to *hft9@cdc.gov.* Telephone and facsimile submissions cannot be accepted.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: November 30, 2012.

Cathy Ramadei,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 2012–29478 Filed 12–5–12; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–1086]

Compliance Guidance for Small Business Entities on Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use; Notice of Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a compliance guidance for small business entities entitled ''Labeling and Effectiveness Testing: Sunscreen Drug Products for Over-the-Counter Human Use; Small Entity Compliance Guide.'' This guidance is intended to help small businesses understand and comply with the requirements of the final rule addressing labeling and effectiveness testing requirements for over-the counter (OTC) sunscreen drug products. The guidance describes the requirements of the final rule in plain language and provides answers to common questions on how to comply with the rule. This guidance was prepared in accordance with the Small Business Regulatory Enforcement Fairness Act.

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

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Reynold Tan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5493, Silver Spring, MD 20993–0002, 301–796–1009.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a compliance guidance for small business entities entitled ''Labeling and Effectiveness Testing: Sunscreen Drug Products for Over-the-Counter Human Use; Small Entity Compliance Guide.'' This guidance summarizes the June 17, 2011, final rule (76 FR 35620) regarding labeling and testing requirements for OTC sunscreen drug products. Under the 2011 sunscreen final rule, required and permitted labeling is based upon the results of effectiveness testing. The effectiveness testing consists of a sun protection factor (SPF) Test and a Broad Spectrum (ultraviolet A (UVA) and ultraviolet B (UVB) protection) Test. In addition, a test demonstrating water resistance that accompanies the SPF Test to ensure retention of SPF

protection while swimming or sweating is described. The 2011 sunscreen final rule makes the following changes to OTC sunscreen drug product regulations:

- Requires that OTC sunscreen drug products follow Drug Facts labeling content and format requirements in § 201.66 (21 CFR 201.66).
- Establishes new labeling requirements for marketed OTC sunscreen drug products set forth in § 201.327 (21 CFR 201.327).
- Revises SPF, broad spectrum, and water-resistant testing requirements and the indications and claims allowed based upon the results of these tests in § 201.327(i) and (j).

FDA is issuing this compliance guidance for small business entities as a level 2 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on the testing requirements for OTC sunscreen drug products and revision of labeling requirements for OTC sunscreen drug products. 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. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in § 201.327 have been approved under OMB control number 0910–0717.

III. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov.* 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, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: November 30, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–29462 Filed 12–5–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–1135]

Guidance for Industry on Limiting the Use of Certain Phthalates as Excipients in Center for Drug Evaluation and Research-Regulated Products; 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 ''Limiting the Use of Certain Phthalates as Excipients in CDER-Regulated Products.'' This guidance provides the pharmaceutical industry with the Center for Drug Evaluation and Research's (CDER's) current thinking on the potential human health risks associated with exposure to dibutyl phthalate (DBP) and di(2-ethylhexyl) phthalate (DEHP). In particular, the guidance recommends that the pharmaceutical industry avoid the use of these two specific phthalates as excipients in CDER-regulated drug and biologic products, including prescription and nonprescription products.

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

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

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

FOR FURTHER INFORMATION CONTACT: Laurie Muldowney, Center for Drug Evaluation and Research (HFD–003), Food and Drug Administration, Bldg. 51, Rm. 4154, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1571.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Limiting the Use of Certain Phthalates as Excipients in CDER-Regulated Products.'' This guidance provides the pharmaceutical industry with CDER's current thinking on the potential human health risks associated with exposure to DBP and DEHP. In particular, the guidance recommends that the pharmaceutical industry avoid the use of these two specific phthalates as excipients in CDER-regulated drug and biologic products, including prescription and nonprescription products. The recommendations in this guidance do not address the use of DBP or DEHP in other types of FDA-regulated products or exposure to DBP or DEHP due to the presence of any of these compounds as an impurity—including as a result of leaching from packaging materials and delivery systems.

Phthalate esters (phthalates) are synthetic chemicals with a broad spectrum of uses. Phthalates are found in certain pharmaceutical formulations, primarily as a plasticizer in enteric-coatings of solid oral drug products to maintain flexibility, but they also may be used for different functions in other dosage forms. Phthalates also are found in other products for uses such as softeners of plastics, solvents in perfumes, and additives to nail polish, as well as in lubricants and insect repellents.

Phthalates have been studied extensively in animals, and DBP and DEHP have been shown to be developmental and reproductive toxicants in laboratory animals. While the data in humans are less clear, epidemiological studies suggest that certain phthalates may affect reproductive and developmental outcomes. Other studies have confirmed the presence of DBP and DEHP in amniotic fluid, breast milk, urine, and serum.

Data from the National Health and Nutrition Examination Survey indicate widespread exposure of the general population to phthalates. Humans are exposed to phthalates by multiple