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

routes, including inhalation, ingestion, and to a lesser degree absorption through the skin. Several observational human studies have reported an association between exposure to certain phthalates and adverse developmental and reproductive effects. The ubiquitous presence of phthalates in the environment and the potential consequences of human exposure to phthalates have raised concerns, particularly in vulnerable populations such as pregnant women and infants.

Although the currently available human data are limited, the Agency has determined that there is evidence that exposure to DBP and DEHP from pharmaceuticals presents a potential risk of developmental and reproductive toxicity. While it is recognized that drug products may carry inherent risks, DBP and DEHP are used as excipients, and safer alternatives are available. Therefore, the Agency recommends avoiding the use of DBP and DEHP as excipients in CDER-regulated drug and biologic products.

These recommendations apply to CDER-regulated drug and biologic products that are under development (i.e., investigational new drugs), nonapplication products (e.g., over the counter monograph products), and both marketed approved products and those currently under review for marketing consideration (i.e., new drug applications, abbreviated new drug applications, and biologics license applications).

There are alternatives to DBP and DEHP for use as excipients in CDER-regulated products. Manufacturers with products that contain DBP or DEHP should consider alternative excipients and determine if the alternative excipient they plan to use has been used in similar CDER-approved products and at what level.

The Inactive Ingredients Database provides information on excipients present in FDA-approved drug products, and this information can be helpful in developing drug products. As manufacturers reformulate their products, the listings for DBP and DEHP will be removed from the Inactive Ingredients Database.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on limiting the use of certain phthalates as excipients in CDER-regulated 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. 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.*

III. 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) and have been approved under OMB control numbers 0910–0014 and 0910–0001.

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. 2012–29461 Filed 12–5–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Health Resources and Services Administration (HRSA) will submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB). Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. To request a copy of the clearance requests submitted to OMB for review, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Office at (301) 443–1984.

Information Collection Request Title: Health Center Controlled Networks (OMB No. 0915-xxxx) NEW

Abstract: One goal of the Health Resources and Services Administration (HRSA) is to ensure that all Health Center Program grantees effectively implement health information technology (HIT) systems that enable all providers to become meaningful users of HIT, including Electronic Health Records (EHR), and use those systems to increase access to care, improve quality of care, and reduce the costs of care delivered. The Health Center Controlled Network (HCCN) program serves as a major component of HRSA's HIT initiative to support these goals. The HCCN model focuses on the integration of certain functions and the sharing of skills, resources, and data to improve health center operations and care provision, and to generate efficiencies and economies of scale. Through this grant, HCCNs will provide support for the adoption, implementation, and meaningful use of HIT to improve the quality of care provided by existing Health Center Program grantees (i.e., Section 330 funded health centers) by engaging in the following program components:

- *Adoption and Implementation:* Assist participating health centers with effectively adopting and implementing certified EHR technology.
- *Meaningful Use:* Support participating health centers in meeting Meaningful Use requirements and accessing incentive payments under the Medicare and Medicaid EHR Incentive Programs.
- *Quality Improvement (QI):* Advance participating health centers' QI initiatives to improve clinical and operational quality, including Patient Centered Medical Home (PCMH) recognition.

HRSA plans to collect and evaluate network outcome measures. HRSA also plans to require that HCCNs report such measures to HRSA in annual work plan updates as part of their annual, non-competing continuation progress reports through an electronic reporting system. The work plan updates will include information on grantees' plans and progress on the following: