container/closure system are considered to be manufacturers, whether or not that packaging is done pursuant to a contract or by the applicant itself.

3. Sites that are identified in a generic drug submission and pursuant to a contract with the applicant remove the drug from a primary container/closure system and subdivide the contents into a different primary container/closure system (contract repackagers).

4. Bioequivalence (BE)/bioavailability (BA) sites that are identified in a generic drug submission and conduct clinical BE/BA testing (i.e., clinical research organizations), bioanalytical testing of samples collected from clinical BE/BA testing, and/or in vitro BE testing.

5. Sites that are identified in a generic drug submission and perform testing of one or more attributes or characteristics of the FDF or the API pursuant to a contract with the applicant to satisfy a current good manufacturing practice testing requirement (excluding sites that are testing for research purposes only).

**II. What type of information must be submitted?**

The information required to be submitted is identified in GDUFA SPL Industry Technical Specification Information document available at *www.fda.gov/gdufa.* Note that the name and contact information for both the registrant owner and the facility, if they are different, must be submitted. This information includes the type of business operation, and, if applicable, the Data Universal Numbering System (DUNS) number(s) and the Facility Establishment Identifier (FEI). A DUNS number is a unique nine-digit sequence provided by Dun & Bradstreet, Inc. An FEI is a unique identifier designated by FDA to assign, monitor, and track inspections of regulated firms. Business entities will also be asked if they manufacture drugs other than generics.

A facility or site that has previously registered with FDA (under section 510 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act), can verify its DUNS number(s) and FEI(s) on FDA's registration site for drug establishments available at *http://www.accessdata.fda.gov/scripts/cder/drls/default.cfm.* Information on obtaining a DUNS number or FEI(s) is provided in the draft guidance for industry entitled ''Self-Identification of Generic Drug Facilities, Sites and Organizations,'' available at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.* FDA encourages business entities to obtain the necessary information as soon as possible to avoid delay.

**III. What is the means and format for submission?**

The new electronic self-identification process will be familiar to many business entities who have previously submitted information to FDA electronically. Self-identification files should be formatted in the same electronic messaging standard used for drug registration and listing information and for the content of labeling for abbreviated new drug applications (ANDAs). This standard known as Health Level Seven SPL allows information to be exchanged, searched, and combined with other data sources in a manner that supports health information technology initiatives to improve patient care.

The required information may be submitted using any of the following tools to generate a self-identification SPL file:

1. eSubmitter tool, a free stand-alone application available at *http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm108165.htm.* Step-by-step instructions for electronically creating, validating, and submitting self-identification information through eSubmitter are available in ''eSubmitter Quick Guide—Generic Drug Facility Self-Identification'' available at *http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm274477.htm;* or

2. Xforms, a free tool for generating SPL files available at *http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm189651.htm.* Step-by-step instructions for electronically creating, validating, and submitting self-identification information using Xforms are available at *http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm;* or

3. Software tools developed internally by generic manufacturers utilizing the SPL technical specifications. Additional information is available at *http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm.*

4. Other commercially available applications (e.g., vendor tools).

Once a self-identification SPL file is created and finalized, transmit the file to FDA through the ESG, FDA's electronic information portal. More information on ESG procedures and process is available on the Electronic Submission Gateway Web site (*http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm*).

**IV. What is the penalty for failing to self-identify?**

Under GDUFA, if a facility fails to self-identify, all FDF or API products manufactured at the facility and all FDFs containing APIs manufactured at the facility will be deemed misbranded. It is a violation of Federal law to ship misbranded products in interstate commerce or to import them into the United States. Such a violation can result in prosecution of those responsible, injunctions, or seizures of the misbranded products. Products that are deemed misbranded because of failure of the facility to self-identify are subject to being denied entry into the United States.

Dated: September 28, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2012–24326 Filed 10–1–12; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2012–D–0971; Formerly Docket FDA–2008–N–0041; Formerly 2008N–0004]**

### Guidance for Industry on Acute Bacterial Otitis Media: Developing Drugs for Treatment; 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 ''Acute Bacterial Otitis Media: Developing Drugs for Treatment.'' This guidance addresses FDA's current thinking regarding the overall development program and clinical trial designs for drugs to support an indication for the treatment of acute bacterial otitis media (ABOM). This guidance finalizes the revised draft guidance of the same name issued on January 18, 2008.

**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:** Joseph G. Toerner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6244, Silver Spring, MD 20993–0002, 301–796–1300.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a guidance for industry entitled ''Acute Bacterial Otitis Media: Developing Drugs for Treatment.'' The purpose of this guidance is to assist sponsors in the overall clinical development of drugs to support an indication for the treatment of ABOM, defined in the guidance as ''the recent or acute onset of inflammation of the middle ear caused by a bacterial pathogen.'' This guidance finalizes the revised draft guidance issued on January 18, 2008, which in turn revised the draft guidance for industry entitled ''Acute Otitis Media—Developing Antimicrobial Drugs for Treatment'' issued in 1998. Changes from the revised draft guidance are incorporated in the appropriate sections of the guidance and are based on comments received to the docket for the draft guidance. In addition, developments in scientific and medical information and technology in the treatment of ABOM are included in this guidance. This guidance fulfills the statutory requirement described in the Food and Drug Administration Amendments Act of 2007 that directed FDA to update the guidance within 5 years.[1] This guidance also responds to the requirement set forth in the Food and Drug Administration Safety and Innovation Act of 2012 that FDA review guidances for the conduct of clinical trials with respect to antibacterial and antifungal drugs and revise such guidances as appropriate.[2]

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 developing drugs for the treatment of ABOM. 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 that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under 0910–0014 and 0910–0001, respectively. The collections of information referred to in the guidance for clinical trial sponsors entitled ''Establishment and Operation of Clinical Trial Data Monitoring Committees'' have been approved under 0910–0581.

## 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: September 26, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2012–24211 Filed 10–1–12; 8:45 am]

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[1] See Title IX, section 911, of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85).

[2] See Title VIII, section 804(a)(1), of the Food and Drug Administration Safety and Innovation Act of 2012 (Pub. L. 112–144).

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Agency Information Collection Activities: Submission for OMB Review; Comment Request

The Health Resources and Services Administration (HRSA) periodically publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). 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.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

**Proposed Project: Healthy Weight Collaborative Evaluation (OMB No. 0915–xxxx)—[NEW]**

*Background:* Supported by the Prevention and Public Health Fund created by Section 4002 of the Affordable Care Act, HRSA awarded $5 million to the National Initiative for Children's Healthcare Quality (NICHQ) to create the Collaborative for Healthy Weight, a national initiative to bring together primary care providers, public health professionals, and leaders of community-based organizations to use quality improvement methods to address the obesity epidemic in communities across the country. A key part of that initiative was creation of the Healthy Weight Collaborative (HWC), a quality improvement project working with 50 community teams to identify, test, and evaluate a national ''change package'' of evidence-based program and policy interventions to address childhood obesity. The HWC is being implemented in two consecutive phases, each with a series of learning sessions and action periods. The first phase (July 2011 to July 2012) includes 10 community teams; the second phase (March 2012 to March 2013) includes 40 additional teams.

*Purpose:* The purpose of this evaluation is to assess the quality and effectiveness of the HWC. This one-year information collection will supplement the analysis of existing quantitative HWC administrative and team data by collecting primary data using individual and group interviews with two groups of stakeholders: (a) NICHQ project leadership, staff, and faculty; and (b) community team members at 11 selected sites (four Phase 1 teams and seven Phase 2 teams). Data from these interviews will be used to evaluate the quality and effectiveness of the HWC. NICHQ leadership, staff, and faculty interview topics include: the design and implementation of the HWC project; the content and quality of the HWC learning sessions, coaching assistance, and other action period activities; the community teams' experiences implementing the