This list will thus contain DMF numbers for those DMFs for which the fee has been paid and which have successfully undergone the initial completeness assessment. Note that these provisions do not apply to Type II API DMFs that are not intended to be referenced in an ANDA, ANDA amendment, or ANDA PAS.

Fee amounts and the due date for the fee will be announced in a separate **Federal Register** notice or notices.

For DMFs that fail the initial completeness assessment, FDA will issue a letter notifying the holder of the DMF that the DMF is incomplete and identifying missing elements in the DMF that must be addressed. Once the DMF is amended, FDA will re-evaluate it for completeness. This draft guidance describes the criteria that FDA will use in its initial completeness assessment of Type II API DMFs to be referenced in generic drug submissions.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on initial completeness assessments of Type II API DMFs to be referenced in generic drug submissions. 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. 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 28, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–24325 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–N–1006]

Generic Drug Facilities, Sites and Organizations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of Requirement.

SUMMARY: The Food and Drug Administration (FDA) is notifying generic drug facilities, and certain sites and organizations identified in a generic drug submission, that they must provide identification information to FDA. This information is required to be submitted to the FDA annually under the Generic Drug User Fee Act Amendments of 2012 (GDUFA) included in the Food and Drug Administration Safety and Innovation Act (FDASIA). This notice is intended to help organizations ascertain if they need to self-identify with the FDA, determine what information they are required to submit, and familiarize themselves with the means and format for submitting the required information.

DATES: For fiscal year 2013, identification information must be submitted by December 3, 2012. For each subsequent fiscal year, identification information must be submitted, updated, or reconfirmed on or before June 1 of the preceding fiscal year.

ADDRESSES: Electronic tools for submitting the required information may be found at the following Web sites:

- *eSubmitter tool: http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm108165.htm.*
- *Structured Product Labeling (SPL) Xforms: http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm189651.htm.*

Step-by-step instructions for electronically creating, validating, and submitting self-identification information are available at *www.fda.gov/gdufa.* Technical specifications for self-identification are also available at *www.fda.gov/gdufa.* Once finalized, the file should be transmitted to FDA through the Electronic Submissions Gateway (ESG), FDA's electronic information portal. Information on the ESG is available at *http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm.*

FOR FURTHER INFORMATION CONTACT: Jaewon Hong, Center for Drug Evaluation and Research (HFD–300), Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 1–866–405–5367 or 301–796–6707.

SUPPLEMENTARY INFORMATION: On July 9, 2012, GDUFA (FDASIA, Title III) (Pub. L. 112–144, Title III) was signed into law by the President. GDUFA requires that generic drug facilities, and certain sites and organizations identified in a generic drug submission, provide identification information annually to FDA. This notice specifies who is required to self-identify, the type of information to be submitted, the means and format for submission of this information, and the penalty for failing to comply. Additional information is contained 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.* This self-identification information will assist in constructing an accurate inventory of facilities, sites and organizations involved in the manufacture of generic drugs. Among other things, the identification information may be used by FDA for purposes including setting fee amounts and targeting inspections.

I. Who is required to self-identify?

The following types of generic industry facilities, sites, and organizations are required to be identified to FDA:

1. Facilities identified, or intended to be identified in at least one generic drug submission that is pending or approved to produce a finished dosage form (FDF) of a human generic drug or an active pharmaceutical ingredient (API) contained in a human generic drug. Thus, facilities engaged in manufacturing or processing a generic API or FDF must be identified. For purposes of self-identification and payment of fees, GDUFA defines API and FDF manufacturers differently from the way they have been defined historically. The GDUFA definitions are included 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.*

2. Sites and organizations that package the FDF of a human generic drug into the primary container/closure system and label the primary container/closure system. Sites and organizations that package the FDF of a human generic drug into the primary container/closure system and label the primary

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**