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 This draft guidance describes the criteria that FDA will use in its initial completeness assessment of Type II API DMFs to be referenced in generic drug submissions.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency’s current thinking on initial completeness assessments of Type II API DMFs to be referenced in generic drug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


Leslie Kux,
Assistant Commissioner for Policy.

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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/drbs/default.cfm. Information on obtaining a DUNS number(s) and FEI(s) on FDA’s registration site for drug establishments available at http://www.fda.gov/Drugs/GuidanceRegulatoryInformation/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:


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 FDF's 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.


Leslie Kux,
Assistant Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration


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 20993–0602. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY