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 [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. For each subsequent fiscal year, identification information must be submitted, updated, or reconfirmed on or before June 1 of the preceding the 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:

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SUPPLEMENTARY INFORMATION: On July 9, 2012, GDUFA (FDASIA, Title III)) (Public Law 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.

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