4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0391]

Generic Drug Facilities, Sites, and Organizations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the generic drug facility self-identification reporting period for fiscal year (FY) 2014 will begin on May 1, 2013, and close on June 1, 2013. Generic drug facilities, certain sites, and organizations identified in a generic drug submission are required by the Generic Drug User Fee Amendments of 2012 (GDUFA) to submit, update, or reconfirm identification information to FDA annually.

DATES: For FY 2014, identification information must be submitted, updated, or reconfirmed between May 1, 2013, and June 1, 2013.

ADDRESSES: Electronic tools for submitting the required information may be found on FDA's Web site at the following addresses:

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

Other applications are available commercially.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

GDUFA (Public Law 112-144, Title III) was signed into law by the President on July 9, 2012, as part of the Food and Drug Administration Safety and Innovation Act. GDUFA is designed to speed the delivery of safe and effective generic drugs to the public and reduce costs to industry. GDUFA enables FDA to assess user fees to fund critical and measurable enhancements to FDA's generic drugs program. GDUFA will also significantly improve global supply chain transparency by requiring owners of facilities producing generic drug products and active pharmaceutical ingredients and certain other sites and organizations that support the manufacture or approval of these products to electronically self-identify with FDA and update that information annually.

Annual self-identification is required for two purposes. First, it is necessary to determine the universe of facilities required to pay user fees. Second, self-identification is a central component of an effort to promote global supply chain transparency. The information provided through self-identification enables quick, accurate, and reliable surveillance of generic drugs and facilitates inspections and compliance.

Persons who self-identified for FY 2013 must self-identify again for FY 2014 between May 1, 2013, and June 1, 2013. Additional information including who is required to self-

identify, how the information is submitted to FDA, the penalty for failure to self-identify, and the technical specifications are available on http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/default.htm.

Please note that registration and listing under section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) is a different process than self-identification under GDUFA. Many persons will thus be required to submit information separately to the respective systems. Each system populates its own database to meet unique requirements and deadlines. Both, however, are built on the same platform and based on the same technical standards.

Dated: April 10, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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