DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA–2013–N–0294]

Submission of New Drug Application/Abbreviated New Drug Application Field Alert Reports: Notice of Form FDA 3331—Automated Pilot Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a pilot program to test an XML (extensible markup language)-enabled Adobe PDF form, Form FDA 3331—Automated to submit new drug application (NDA) and abbreviated new drug application (ANDA) Field Alert Reports (FARs) as required by FDA regulations. This pilot program is intended to provide FDA with information to allow the Agency to modernize the FAR submission and review pathway and will permit integration with electronic archive filing systems.

DATES: The XML-enabled Adobe PDF form, Form FDA 3331—Automated, will be available for piloting between May 1, 2013, and January 1, 2014.

ADDRESSES: Electronic or written general comments regarding the pilot may be submitted to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The automated form, detailed instructions for use, and frequently asked questions are available at http://www.fda.gov/ICECI/Inspections/IOM/CDER/ucm347604.htm.

Questions or feedback about the pilot program should be sent to district Drug Field Alert Monitor or the CDER’s Office of Medical Products and Tobacco. Contact information for each district office and to CDER’s Office of Medical Products and Tobacco is available on FDA’s Web site at http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm347604.htm.

II. Comments and Other Feedback

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written general comments to the Division of Dockets Management (see ADDRESSES). 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.

Participants should contact their district Drug Field Alert Monitors for questions or feedback about the pilot program. Contact information for each district Drug Field Alert Monitor is available on FDA’s Web site at http://www.fda.gov/ICECI/Inspections/IOM/CDER/ucm124063.htm. CDER has also established an email account, CDER-FAR-XML@fda.hhs.gov, to receive feedback on participants’ experiences using the XML-enabled Form FDA 3331—Automated.

III. The Paperwork Reduction Act of 1995

This notice refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in Form FDA 3331 has been approved under OMB control number 0910–0001.

Dated: April 26, 2013.

Leslie Kux,
Assistant Commissioner for Policy.

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