



4160-01-P

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/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm347604.htm>.

Questions or feedback about the pilot program should be sent to district Drug Field Alert Monitors (contact information for each of these individuals is available on FDA's Web site at <http://www.fda.gov/ICECI/Inspections/IOM/ucm124063.htm>). FDA's Center for Drug Evaluation and Research (CDER) has also established an email account, [CDER-FAR-XML@fda.hhs.gov](mailto:CDER-FAR-XML@fda.hhs.gov), to receive feedback on participants' experiences using the XML-enabled Form FDA 3331-Automated.

FOR FURTHER INFORMATION CONTACT:

Mark Browning,  
Center for Drug Evaluation and Research,  
Food and Drug Administration,  
10903 New Hampshire Ave.,  
Silver Spring, MD 20993,  
301-796-5342.

SUPPLEMENTARY INFORMATION:

I. Background

This pilot program seeks to modernize the FAR submission and review pathway using an XML-enabled PDF form to enable integration with electronic archive filing systems and simplify data integration across the enterprise. Under existing procedures, firms typically submit FARs via fax or scanned copy to their respective FDA district offices, and the district offices then provide them to CDER for additional review and analysis. Under this pilot program, participants will be able to send the FAR report simultaneously to the selected FDA district office and to CDER's Office of Compliance, allowing for improved coordination within the Agency as well as more efficient reporting by industry. The pilot program will also offer industry participants the

opportunity to provide the Agency with feedback regarding the use of the automated form. FDA will take industry feedback into account when improving the FAR reporting process overall.

The pilot is open to all NDA and ANDA holders. Participation in the pilot program is voluntary and no additional software or licenses are needed to use the proposed Form FDA 3331-Automated. For the period of the pilot program, firms that elect to participate must continue to submit a signed Form FDA 3331 (whether the traditional or the automated version) via email, along with the pilot automated form. This parallel process during the pilot program will ensure delivery of all field alert reports and allow FDA to evaluate the utility of an automated form.

The pilot program will run for 8 months following the date of the Federal Register Notice and may be extended as needed to accrue sufficient reports and experience for a meaningful evaluation. After the pilot concludes, CDER and the Office of Regulatory Affairs will evaluate the forms submitted along with any direct industry feedback about using the automated form. If the pilot is successful, FDA would likely seek to adopt a more permanent, required electronic reporting system, which would be implemented in accordance with existing regulation- and guidance-making processes, as needed.

The automated form, detailed instructions for use, and frequently asked questions are 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/ucm124063.htm>. CDER has also established an email account, [CDER-FAR-XML@fda.hhs.gov](mailto: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.