4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-1524]

Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities; Final Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a final guidance for industry entitled "Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities." This guidance describes the conditions under which FDA does not intend to take action for violations of certain provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), when a State-licensed pharmacy, a Federal facility, or an outsourcing facility repackages certain human drug products.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may

not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on http://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2014-D-1524 for "Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on http://www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Sara Rothman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 5197, Silver Spring, MD 20993, 301-796-3110.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled "Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities." FDA regards repackaging as the act of taking a finished drug product from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the drug. If a drug is manipulated in any other way, including if the drug is reconstituted, diluted, mixed, or combined with another ingredient, that act is not considered repackaging.

Repackaged drugs are generally not exempt from any of the provisions of the FD&C Act related to the production of drugs. For example, repackaged drugs are generally subject to the premarket approval, misbranding, adulteration, and drug supply chain security provisions of the FD&C Act, including section 505 (concerning new drug applications), section 502(f)(1) (concerning labeling with adequate directions for use), section 501(a)(2)(B) (concerning current

good manufacturing practice (CGMP)), and section 582 (drug supply chain security requirements) (21 U.S.C. 355, 352(f)(1), 351(a)(2)(B), and 360eee-1).

Further, drugs that are repackaged are not subject to sections 503A and 503B of the FD&C Act (21 U.S.C. 353a and 353b). Therefore, drugs repackaged by state-licensed pharmacies, Federal facilities, or outsourcing facilities are not eligible for the exemptions provided under those sections.

This guidance describes the conditions under which FDA does not intend to take action for violations of sections 505, 502(f)(1), 582, and, where specified in the guidance, section 501(a)(2)(B) of the FD&C Act, when a state-licensed pharmacy, Federal facility, or outsourcing facility repackages certain drug products.

In the Federal Register of February 19, 2015 (80 FR 8884), FDA issued a notice announcing the availability of the draft version of this guidance. The comment period on the draft guidance ended on May 20, 2015. FDA received approximately 625 comments on the draft guidance. In response to received comments or on its own initiative, FDA made several changes. For example, FDA removed from the guidance the condition concerning "anticipatory repackaging" (repackaging before the receipt of a patient-specific prescription) of no more than a 14-day supply. FDA made this change partly in response to comments indicating that pharmacies sometimes need to repackage more than a 14-day supply of repackaged drug products in advance of a prescription. FDA also revised the conditions concerning beyond-use-dates (BUDs) for repackaged drugs to reflect BUDs for compounded drugs in, as applicable, United States Pharmacopeia (USP) Chapter <795>, the USP's proposed revision to Chapter <797>, and FDA's guidance concerning current good manufacturing practice requirements for outsourcing facilities.

FDA received comments on the draft guidance from hospital organizations regarding the potential implications of the proposed policies in the draft guidance concerning patient-specific prescriptions for drugs repackaged for in-patient settings. The final guidance notes that FDA is considering the applicability of the policies described in this guidance to in-patient settings, including long-term care facilities and hospitals, and intends to address these issues in separate guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the current thinking of FDA on repackaging human drug products by pharmacies, Federal facilities, and outsourcing facilities. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501-3520). Under the PRA, Federal Agencies must obtain approval from OMB for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, in the Federal Register of February 19, 2015, we gave interested persons 60 days to comment on the information collection provisions in the draft guidance (80 FR 8884 at 8885).

After publishing the 60-day notice requesting public comment, section 3507 of the PRA (44 U.S.C. 3507) requires Federal Agencies to submit the proposed collection to OMB for review and clearance. In compliance with 44 U.S.C. 3507, we will be submitting a proposed collection of information to OMB for review and clearance. FDA is issuing this guidance as final with portions of it subject to OMB approval of the collection of information and shaded gray. Those provisions that are shaded gray and subject to OMB approval will be final if the collection of information is approved. If the collection is approved, FDA will publish a notice in the Federal Register concerning OMB approval and providing an OMB control number for these provisions.

The guidance also references registration and adverse event reporting for outsourcing facilities. The collections of information for outsourcing facility registration have been approved by OMB under OMB control number 0910-0777. The collections of information for adverse event reporting by outsourcing facilities have been approved by OMB under OMB control number 0910-0800.

III. Electronic Access

Persons with access to the Internet can obtain the document at either http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.

Dated: January 10, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017-00723 Filed: 1/12/2017 8:45 am; Publication Date: 1/13/2017]