

not reached, each party may use its statutory and other rights as specified in the "Preservation of Rights" section below. This decision making process will be evaluated by the Committee after one full year of its operation.

Meeting Schedule and Logistics: The Committee will meet on a quarterly basis or more frequently by consensus of its members. The Committee will normally meet at ACF Central Office in Washington, DC, but may also meet at another location by consensus. If a Committee member is unable to physically attend a meeting, he/she may participate by phone or video teleconferencing. The date and time for any meetings will be established by mutual agreement. Committee meetings may be held in conjunction with other meetings where it is deemed cost effective and there is consensus.

Working Groups: The Committee has the authority to form workgroups that may include individuals who are not members of the Committee. Any such workgroups will be given their charge and/or responsibilities from the LMC in writing. Non-Committee member bargaining unit participants on such groups will be appointed by NTEU and will be provided appropriate official time to participate in workgroup activities.

Support: The Committee will use the services of a facilitator trained in interest-based bargaining techniques as needed. The appointed Executive Secretary will provide administrative support to the Committee. Such support shall include creation and dissemination of meeting agenda and minutes, announcements of meetings, and other matters as determined by the Committee. The Agency will make available the use of video and telephone conferencing for the participation of all committee members at meetings. The Agency will provide meeting rooms for LMC meetings.

Participation: The Agency encourages the use of video and telephone conferencing for the participation of those members who are domiciled outside the 50 mile radius of Washington, DC, and will provide the necessary equipment to facilitate the process. Union representatives will be granted official time for preparation and participation in the meetings, pursuant to Article 10 of the Collective Bargaining Agreement. The Agency will pay for all reasonable local travel expenses, namely transportation and parking. For those participants domiciled outside the 50 mile radius, the Agency agrees to reimburse the Union representatives 50 percent of reasonable travel expenses, including transportation, lodging, and per diem.

In the interest of facilitating the working relations among the members, the Agency agrees to assume the full costs associated with travel, including transportation, lodging and per diem for participants for the first scheduled meeting of the Committee. For all subsequent meetings, the Agency will reimburse the Union representatives for 50 percent as stated above.

Agenda Development and Dissemination: The LMC's potential agenda items will be submitted to the Co-Chairs who will mutually establish a formal agenda for the

next LMC meeting. The formal agenda will be distributed to all LMC members at least three work days prior to the next LMC meeting. For issues requiring a decision by the LMC, all proposals or related materials will be distributed to the LMC members as soon as possible but no later than seven work days prior to the meeting at which the decision will need to be made.

Communication: Final, approved minutes of the Committee will be disseminated and made available to all ACF employees via methods determined by the Committee.

Evaluation

The Committee will evaluate its progress on an annual basis. It will determine whether to renew its procedures and/or to make changes in any aspect of the LMC.

Preservation of Rights

Cooperation is not intended to supplant the decision-making authority, or to usurp the responsibility of agency management, but to further involve ACF employees in developing ACF decisions through the active and systematic participation of NTEU and those it represents who perform ACF's work. This LMC is based on the belief that NTEU participation in ACF decision-making will promote decisions of such a nature that the need for formal bargaining will be reduced and, where bargaining becomes necessary, will inform and facilitate the negotiations.

Accordingly, subject to statute, executive orders, and the collective bargaining agreement, ACF reserves the right to determine whether to implement recommendations arising from the cooperation endeavor, and NTEU reserves the right to bargain concerning the substance, impact and implementation of final ACF decisions prior to implementation. The ACF recognizes its statutory, regulatory, and/or contractual obligations to provide notification to NTEU and to bargain.

Effective Date, Duration, and Modifications

This LMC shall be instituted upon the date the parties have signed the Charter. The partners may amend or supplement this Agreement at any time upon consensus. This Agreement may be terminated by either of the parties to this Agreement. Termination by either party shall be provided in writing and shall be considered effective exactly 30 calendar days after receipt by the recipient party. Notification of termination shall be sent out in a written notice to all ACF staff within 10 days of the termination and shall be published in the **Federal Register** within 30 days of the termination.

On behalf of NTEU and ACF, the undersigned execute this Agreement on this 30th day of December, 2016, by Anthony Reardon, NTEU National President; Mark H. Greenberg, Acting Assistant Secretary for Children and Families; and Benjamin Goldhaber, Deputy Assistant Secretary for Administration, Administration for Children and Families.

Dated: January 6, 2017.

Mark H. Greenberg,

Assistant Secretary for Children and Families.

[FR Doc. 2017-00655 Filed 1-12-17; 8:45 am]

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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 1–12–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1543]

Nonproprietary Naming of Biological Products; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled “Nonproprietary Naming of Biological Products.” The guidance describes our current thinking on the need for biological products previously and newly licensed under the Public Health Service Act (PHS Act) to bear nonproprietary names that include FDA-designated suffixes. Accordingly, we intend to designate nonproprietary names for originator biological products, related biological products, or biosimilar products which will include a core name and a distinguishing suffix that is devoid of meaning and composed of four lowercase letters. This guidance finalizes the draft guidance issued on August 28, 2015.

FDA is also announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit either electronic or written comments on Agency guidances at any time. Submit written comments on the collection of information by February 13, 2017.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910–New and title “Nonproprietary Naming of Biological Products.” Also include the FDA docket number found in brackets in the heading of this document.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://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 <https://www.regulations.gov>.

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Instructions: All submissions received must include the Docket No. FDA–2013–D–1543 for “Nonproprietary Naming of Biological Products.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

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