development applicants should incorporate pediatric patients for development of systemic drugs for AD. This guidance has only minor editorial changes and finalizes the draft guidance of the same name issued on April 9, 2018 (83 FR 15157) to which no comments were received.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Atopic Dermatitis: Timing of Pediatric Studies During Development of Systemic Drugs.'' 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. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 collections of information related to the burden on the submission of new drug applications in 21 CFR 314.50(d)(7), including pediatric use information, have been approved under OMB control number 0910–0001. The collections of information related to the burden on the submission of investigational new drug applications in § 312.47(b)(1)(iv) (21 CFR 312.47(b)(1)(iv)), including plans for pediatric studies, have been approved under OMB control number 0910–0014. The collections of information related to the burden for requesting meetings with FDA about drug development programs in §§ 312.47 and 312.82 have been approved under OMB control number 0910–0429. The collections of information related to the burden on the submission of information about expedited review programs for serious conditions and the guidance for industry entitled ''Expedited Programs for Serious Conditions—Drugs and Biologics'' (available at *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm358301.pdf*) have been approved under OMB control number 0910–0765. The collections of information referenced in this guidance that are related to the burden on the submission of biologics license applications covered under 21 CFR part 601, including pediatric use information, have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *https://www.regulations.gov.*

Dated: September 27, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–21519 Filed 10–2–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–3438]

Selection of the Appropriate Package Type Terms and Recommendations for Labeling Injectable Medical Products Packaged in Multiple-Dose, Single-Dose, and Single-Patient-Use Containers for Human Use; 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 final guidance for industry entitled ''Selection of the Appropriate Package Type Terms and Recommendations for Labeling Injectable Medical Products Packaged in Multiple-Dose, Single-Dose, and Single-Patient-Use Containers for Human Use.'' This guidance finalizes the draft guidance issued October 22, 2015, which provides recommendations on the selection of appropriate package type terms and selection of appropriate discard statements for injectable medical products for human use, packaged in multiple-dose, single-dose, and single-patient-use containers.

DATES: The announcement of the guidance is published in the **Federal Register** on October 3, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time 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.*
- 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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2015–D–3438 for ''Selection of the Appropriate Package Type Terms and Recommendations for Labeling Injectable Medical Products Packaged in Multiple-Dose, Single-Dose, and Single-Patient-Use Containers for Human Use.'' 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 Dockets Management Staff 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this 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, or Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, 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: Yana Mille, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4166, Silver Spring, MD 20993, 301–796–1577; or Stephen Ripley, Center for Biologics Evaluation and Research, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Selection of the Appropriate Package Type Terms and Recommendations for Labeling Injectable Medical Products Packaged in Multiple-Dose, Single-Dose, and Single-Patient-Use Containers for Human Use.'' Unsafe injection practices, including the use of needles or syringes for more than one patient or the improper use of medication vials for more than one patient, threaten patient safety and have resulted in multiple blood borne bacterial and viral infection outbreaks. Bacterial and viral infections have been transmitted to patients when single-dose containers were used improperly, the contents became contaminated, and these contents were then administered to multiple patients. Failure to follow standard precautions and aseptic techniques has also been associated with several outbreaks of infections involving multiple-dose vials.

As part of its review of medical products, FDA clears or approves package type terms and discard statements as part of the labeling of injectable medical products. FDA believes that consistent use of correct package type terms and discard statements for injectable medical products for human use will promote their proper use and provide a foundation for educational efforts to reduce the transmission of blood borne pathogens. All the stakeholder comments on the draft guidance were carefully reviewed and, where appropriate, clarifying edits were made in the final guidance. The major change made in response to stakeholder comments on the draft guidance was the addition of a subsection titled ''Addition of a discard statement or changes to an existing discard statement'' to the ''Labeling Requirements and Recommendations'' section of the final guidance.

Specifically, this guidance provides FDA's revised definitions for single-dose and multiple-dose containers as well as the definition for the new package type term single-patient-use container. These containers may be part of a drug, a biological product, or a combination product assigned to FDA's Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, or certain combination products assigned to FDA's Center for Devices and Radiological Health. Marketing applications for such products include new drug applications (NDAs), abbreviated new drug applications (ANDAs), biologics license applications (BLAs), premarket approval applications (PMAs), premarket notifications under the Federal Food, Drug, and Cosmetic Act (FD&C Act), and requests for classification submitted under the FD&C Act De Novo request.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on the selection of the appropriate package type terms and recommendations for labeling injectable medical products packaged in multiple-dose, single-dose, and single-patient-use containers for human use. 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. This guidance is not subject to Executive Order 12866.

II. The Paperwork Reduction Act of 1995

This guidance 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 collections of information discussed in this guidance have been approved under the following OMB control numbers: OMB control number 0910–0001 for NDAs, ANDAs, supplements to NDAs and ANDAs, and annual reports; OMB control number 0910–0572 for prescription drug product labeling; OMB control number 0910–0338 for BLA, BLA supplements, and annual reports; OMB control number 0910–0120 for premarket notifications (510(k)s); OMB control number 0910–0231 for PMAs; OMB control number 0910–0485 for medical device labeling; and OMB control number 0910–0577 for prominent and conspicuous mark of manufactures on single-use devices.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *https://www.regulations.gov.*

Dated: September 27, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–21531 Filed 10–2–18; 8:45 am]

BILLING CODE 4164–01–P