• Section 505 (21 U.S.C. 355) (concerning the approval of drugs under new drug applications or abbreviated new drug applications); and

• Section 582 (21 U.S.C. 360eee–1) (concerning drug supply chain security requirements).

One of the conditions that must be met for a compounded drug product to qualify for the exemptions under section 503B of the FD&C Act is that the drug is not essentially a copy of one or more approved drugs (section 503B(a)(5)).

Section 503B(d)(2) defines essentially a copy of an approved drug as:

• A drug that is identical or nearly identical to an approved drug, or a marketed drug not subject to section 503(b) and not subject to approval in an application submitted under section 505, unless, in the case of an approved drug, the drug appears on the drug shortage list in effect under section 506E at the time of compounding, distribution, and dispensing (section 503B(d)(2)(A)) or

• a drug, a component of which is a bulk drug substance that is a component of an approved drug or a marketed drug that is not subject to section 503(b) and not subject to approval in an application submitted under section 505, unless there is a change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug (section 503B(d)(2)(B)).

This guidance sets forth FDA's policies concerning the ''essentially a copy'' provision of section 503B of the FD&C Act.

In the **Federal Register** of July 11, 2016 (81 FR 44879), FDA issued a notice announcing the availability of the draft version of this guidance. The comment period on the draft guidance ended on October 11, 2016. FDA received 29 comments on the draft guidance. In response to received comments or on its own initiative, FDA made several changes. For example, in response to requests in comments for direction on records retention, FDA added a recommendation that compounders maintain the records described in the guidance for at least 3 years. In addition, to address questions raised in comments, FDA clarified that the Agency does not intend to take action against an outsourcing facility for failing to compound in accordance with section 503B(a)(5) if it fills orders for a compounded drug that is essentially a copy of an approved drug that has been discontinued and is no longer marketed.

FDA received comments from hospital organizations regarding the potential implications of proposed policies for the preparation of compounded drugs used in in-patient settings. The final guidance notes that FDA is considering the applicability of the policies described in this guidance to hospitals and health systems. We recognize that this issue is of interest to many stakeholders and will publicly convey our further thinking on the applicability of these policies to hospitals and health systems with an opportunity for comment.

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 ''Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' 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 contains collections of information that are subject to review by OMB under the PRA (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 July 11, 2016, we gave interested persons 60 days to comment on the information collection provisions in the draft guidance.

The information collection provisions in this guidance have been submitted to OMB for review as required by section 3507(d) of the PRA. These provisions are not in effect until they display a currently valid OMB control number. FDA will publish a notice in the **Federal Register** announcing OMB's decision regarding the information collection provisions in this guidance.

III. Electronic Access

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

Dated: January 16, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–00914 Filed 1–18–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1525]

Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application; 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 ''Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application.'' This final guidance describes the conditions under which FDA does not intend to take action against a State-licensed pharmacy, a Federal facility, or an outsourcing facility that mixes, dilutes, or repackages certain biological products outside the scope of an approved biologics license application (BLA). It also describes the conditions under which FDA does not intend to take action when a State-licensed pharmacy, a Federal facility, an outsourcing facility, or a physician prepares prescription sets of allergenic extracts for subcutaneous immunotherapy.

DATES: The announcement of the guidance is published in the **Federal Register** on January 19, 2018.

ADDRESSES: You may submit 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–2014–D–1525 for ''Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application.'' 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 *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 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, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Avenue, 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 draft 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 20903, 301–796–3110; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 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 final guidance for industry entitled ''Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application.'' Certain licensed biological products may sometimes be mixed, diluted, or repackaged in a way not described in the approved labeling for the product to meet the needs of a specific patient. For example, for some biological products there is no licensed pediatric strength and/or dosage form. In addition, there may be certain circumstances when a person would remove a licensed biological product from its original container and place it into a different container(s) (repackage it), in a manner that is not within the scope of the approved labeling for the product. As described in the guidance, mixed, diluted, or repackaged biological products are not eligible for the statutory exemptions available to certain compounded drugs under sections 503A and 503B of the FD&C Act (21 U.S.C. 353a and 353b). In addition, a biological product that is mixed, diluted, or repackaged outside the scope of an approved BLA is considered an unlicensed biological product under section 351 of the Public Health Service (PHS) Act (42 U.S.C. 262).

This guidance describes the conditions under which FDA does not intend to take action for violations of section 351 of the PHS Act, and section 502(f)(1) (21 U.S.C. 352(f)(1)), section 582 (21 U.S.C. 360eee–1), and where specified, section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) of the FD&C Act, when a state-licensed pharmacy, a Federal facility, or an outsourcing facility dilutes, mixes, or repackages certain biological products outside the scope of an approved BLA.

In the **Federal Register** of January 13, 2017 (82 FR 4358), FDA issued a notice announcing the availability of the revised draft version of this guidance. The comment period on the draft guidance ended on March 14, 2017. FDA received 11 comments on the revised draft guidance. In response to received comments or on its own initiative, FDA made revisions to clarify certain points. For example, FDA added a footnote indicating that the Agency is considering the applicability of the policies described in this guidance to hospitals and health systems and intends to address these issues in separate guidance. FDA also clarified that one of the conditions under which the Agency does not intend to take action for the violations listed above is that any components used in mixing or diluting a licensed biological product are sterile, pharmaceutical grade, and otherwise appropriate for such use.

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 mixing, diluting, or repackaging biological products outside

the scope of an approved BLA. 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 January 13, 2017, we gave interested persons 60 days to comment on the information collection provisions in the draft guidance (82 FR 4358 at 4359).

The information collection provisions in this guidance will be submitted to OMB for review as required by section 3507(d) of the PRA. These provisions are not in effect until they display a currently valid OMB control number. FDA will publish a notice in the **Federal Register** announcing OMB's decision regarding the information collection provisions in this guidance.

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 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: January 16, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–00916 Filed 1–18–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–7011]

Laser Products—Conformance With IEC 60825–1 Ed. 3 and IEC 60601–2–22 Ed. 3.1 (Laser Notice No. 56); Draft Guidance for Industry and Food and Drug Administration Staff; 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 the draft guidance entitled ''Conformance with IEC 60825–1 Ed. 3 and IEC 60601–2–22 Ed. 3.1 (Laser Notice No. 56).'' This draft guidance describes the Agency's proposed approach regarding compliance with FDA's performance standards for laser products. FDA believes that under the circumstances described in this guidance, conformance with certain International Electrotechnical Commission (IEC) standards would provide adequate protection of the public health and safety for laser products similar to performance standards in FDA's regulations. Accordingly, FDA does not intend to consider whether firms that comply with the comparable IEC standards discussed in this guidance document also comply with performance standards in FDA's regulations. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by March 20, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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–2017–D–7011 for ''Conformance with IEC 60825–1 Ed. 3 and IEC 60601–2–22 Ed.3.1 (Laser Notice No. 56).'' 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