3520). The collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR 50.23 (Exception from general requirements for informed consent) have been approved under OMB control number 0910–0586; the collections of information in 21 CFR 56.115 (Institutional Review Board records) have been approved under OMB control number 0910–0130; and the collections of information in 21 CFR part 50, subpart B (Informed Consent of Human Subjects) and part 56 (Institutional Review Boards) have been approved under OMB control number 0910–0755.

Dated: January 9, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–00604 Filed 1–12–17; 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Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application; Revised Draft Guidance For Industry; Availability

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a revised draft guidance for industry entitled ''Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application.'' This revised draft guidance describes the conditions under which FDA does not intend to take action against a State-licensed pharmacy, a Federal facility, or an outsourcing facility that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. This revised draft guidance for industry replaces the draft guidance for industry of the same title issued in February 2015.

DATES: Although you can comment on any guidance at any time (*see* 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by March 14, 2017.

ADDRESSES: 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*.
- 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–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 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 *https://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 *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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft 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 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 revised draft 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 draft 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 Federal Food, Drug, and Cosmetic Act (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 draft 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.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance, when finalized, will represent FDA's current thinking on mixing, diluting, and repackaging of biological products not within the scope of the product's approved BLA as described in the approved labeling for the product. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection are given under this section with an estimate of the annual reporting and recordkeeping burdens. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

We invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

The draft guidance includes the following collection of information under the PRA.

One condition described in the draft guidance is that if the labeling for the licensed biological product includes storage and/or handling instructions (*e.g.,* protect from light, do not freeze, keep at specified storage temperature), the labeling for the biological product that is mixed, diluted, or repackaged specifies the same storage conditions.

Another condition described in the draft guidance is that, if the biological product is mixed, diluted, or repackaged by an outsourcing facility, the label on the immediate container (primary packaging, *e.g.,* the syringe) of the mixed, diluted, or repackaged product includes the following information:

- The statement ''This biological product was mixed/diluted by [name of outsourcing facility],'' or ''This product was repackaged by [name of outsourcing facility],'' whichever statement is appropriate;
- The address and phone number of the outsourcing facility that mixed, diluted, or repackaged the biological product;
- The proper name of the original biological product that was mixed, diluted, or repackaged;
- The lot or batch number of the mixed, diluted, or repackaged biological product;
- The dosage form and strength;
- A statement of either the quantity or the volume of the mixed, diluted, or repackaged biological product, whichever is appropriate;
- The date the biological product was mixed, diluted, or repackaged;
- The beyond-use-date (BUD) of the mixed, diluted, or repackaged biological product;
- Storage and handling instructions for the mixed, diluted, or repackaged biological product;
- The National Drug Code (NDC) number of the mixed, diluted, or repackaged biological product, if available; [1]
- The statement ''Not for resale,'' and, if the biological product is distributed by an outsourcing facility other than pursuant to a prescription for an individual identified patient, the statement ''Office Use Only''; and
- If included on the label of the FDA-licensed product from which the biological product is being mixed, diluted, or repackaged, a list of the active and inactive ingredients; and if the biological product is mixed or diluted, a list of any ingredients that appear in the mixed or diluted product in addition to those ingredients that are on the label of the original FDA-licensed biological product.

In addition, the draft guidance includes as a condition for biological products mixed, diluted, or repackaged by an outsourcing facility that, if the immediate product label is too small to bear the active and inactive ingredients, such information should be included on the label of the container from which the individual units are removed for administration (secondary packaging, *e.g.,* the bag, box, or other package in which the mixed, diluted, or repackaged biological products are distributed).

The draft guidance also describes the condition for biological products mixed, diluted, or repackaged by an outsourcing facility that the label on the container from which the individual units are removed for administration

[1] The NDC number of the original licensed biological product should not be placed on the mixed, diluted, or repackaged biological product.

include directions for use, including, as appropriate, dosage and administration, and the following information to facilitate adverse event reporting: *http://www.fda.gov/medwatch* and 1–800–FDA–1088.

Finally, the draft guidance described a condition for biological products repackaged by an outsourcing facility for which the BUD is established based on a stability program conducted in accordance with Appendix A of the draft guidance, that the outsourcing facility maintains records of the testing performed in accordance with Appendix A.

We estimate that annually a total of approximately 15 outsourcing facilities that mix, dilute, or repackage biological products (''Number of Respondents'' in table 1, row 1) will each design, test, and produce approximately five different labels (''Frequency per Disclosure'' in table 1, row 1), for a total of 75 labels that include the information set forth in section III.B of the draft guidance (including directions for use) as well as inclusion of storage and/or handling instructions (''Total Disclosures'' in table 1, row 1). We also estimate that designing, testing, and producing each label will take approximately 0.5 hours (''Hours per Disclosure'' in table 1, row 1). The provision to add *http://www.fda.gov/medwatch* and 1–800–FDA–1088 is not included in this burden estimate because it is not considered a collection of information under the PRA because the information is ''originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

Section III.C of the draft guidance discusses the preparation of prescription sets (*i.e.,* licensed allergenic extracts that are mixed and diluted to provide subcutaneous immunotherapy to an individual patient) by a physician, State-licensed pharmacy, a Federal facility, or outsourcing facility. One of the conditions described in the draft guidance is if the prescription set is mixed or diluted by an outsourcing facility, the label on the immediate container of the prescription set (primary packaging) includes:

- The patient's name as identified on the prescription or order;
- The statement ''This prescription set was prepared by [name of outsourcing facility]'';
- The address and phone number of the outsourcing facility that prepared the prescription set;
- The identity of each allergenic extract in the prescription set and the quantity of each;
- The dilution of each dilution vial;
- The lot or batch number of the prescription set;
- The date the prescription set was prepared;
- The BUD as the expiry date for the prescription set;
- Storage and handling instructions for the prescription set; and
- The statement ''Not for resale.''

Another condition under the draft guidance is that if the prescription set is prepared by an outsourcing facility, the label of the container from which the individual units of the prescription set are removed for administration (secondary packaging) includes the following information to facilitate adverse event reporting: *http://www.fda.gov/medwatch* and 1–800–FDA–1088. Each prescription set prepared by an outsourcing facility is also accompanied by instructions for use.

We estimate that annually a total of approximately five outsourcing facilities that prepare prescription sets (''Number of Respondents'' in table 2, row 1) will each include the information set forth in section III.C of the draft guidance (including directions for use) on the labels, packages, and/or containers of approximately 300 prescription sets (''Frequency per Disclosure'' in table 2, row 1) for a total of 1500 disclosures (''Total Disclosures'' in table 2, row 1). We also estimate that the initial process of designing, testing, and producing, and attaching each label, package, and/or container to each prescription set will take approximately 0.5 hours (''Hours per Disclosure'' in table 2, row 1). The provision to add ''*http://www.fda.gov/medwatch*'' and ''1–800–FDA–1088'' is not included in this burden estimate because it is not considered a collection of information under the PRA because the information is ''originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

We estimate that annually a total of approximately 5 outsourcing facilities that repackage biological products and establish a BUD in accordance with Appendix A (''No. of Recordkeepers'' in table 3) will maintain approximately 150 records of the testing, as described in Appendix A (''total annual records'' in table 3). We estimate that maintaining the records will take approximately 5 minutes per record.

The total estimated third-party disclosure burden resulting from the draft guidance is as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Biological product mixing, diluting, and repackaging	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Designing, testing, and producing the label, container, packages, and/or outer containers for each mixed, diluted, or repackaged biological product.	15	5	75	0.5 (30 minutes)	37.5

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Preparation of prescription sets	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Designing, testing, and producing each label on immediate containers, packages, and/or outer containers.	5	300	1,500	0.5 (30 minutes)	750

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Type of recordkeeping	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Records that the outsourcing facility maintains of the testing performed in accordance with Appendix A of the guidance.	5	30	150	0.083 (5 minutes)	12.5

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The draft guidance also references registration, adverse event reporting, product reporting, and current good manufacturing practice (CGMP) requirements for outsourcing facilities. The collections of information for outsourcing facility registration have been approved by the Office of Management and Budget (OMB) under OMB control number 0910–0777 (79 FR 69859). The collections of information for adverse event reporting by outsourcing facilities have been approved by OMB under OMB control number 0910–0800 (80 FR 60917). In the **Federal Register** of December 4, 2013 (78 FR 72897), FDA estimated the burden resulting from outsourcing facility electronic drug product reporting. In the **Federal Register** of July 2, 2014 (79 FR 37743), FDA estimated the burden resulting from outsourcing facility compliance with CGMP requirements.

IV. Electronic Access

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

Dated: January 10, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–00722 Filed 1–12–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–4645]

180-Day Exclusivity: Questions and Answers; Draft 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 draft guidance for industry entitled ''180-Day Exclusivity: Questions and Answers.'' This draft guidance is intended to address questions that have been raised about the provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) that relate to generic drug exclusivity, which commonly is known as ''180-day exclusivity'' for generic drug products. As a general matter, FDA has implemented these statutory provisions within the context of application-specific decisions. Some FDA decisions have been made publicly available (*e.g.,* in FDA citizen petition responses and documents released in litigation). FDA believes that a guidance for industry that provides answers to commonly asked questions about 180-day exclusivity would enhance transparency and facilitate the development, approval, and timely marketing of generic drug products. FDA intends to update this guidance to include additional questions and answers as appropriate.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by March 14, 2017.

ADDRESSES: 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.*
- 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–2016–D–4645 for ''180-Day Exclusivity: Questions and Answers.'' 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.

- 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