TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

| Compounding MOU between FDA and States | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeping (in Hours) | Total Hours |
|---|---|---|---|---|---|
| State recordkeeping for 3 years of compounding complaints | 25 | 15 | 375 | 1 | 375 |
| Total | 25 | 15 | 375 | 1 | 375 |

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

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

| Compounding MOU between FDA and States | Number of respondents | Number of disclosures per respondent | Total annual disclosures | Average burden per disclosure (in Hours) | Total hours |
|---|---|---|---|---|---|
| State notification to pharmacists, pharmacies, and physicians that its participation in the MOU has been terminated by FDA | 1 | 1 | 1 | 1 | 1 |
| Total | 1 | 1 | 1 | 1 | 1 |

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

## VII. Request for Comments

FDA invites comments from interested persons on the new draft standard MOU that would establish an agreement between the signatory States and FDA regarding the appropriate investigation by such States of complaints relating to compounded human drug products distributed outside the State, and the distribution of inordinate amounts of compounded human drug products interstate. The Agency is providing a 120-day comment period.

After considering any comments on the new draft standard MOU submitted to this docket, FDA intends to finalize the standard MOU and make it available for signature by individual States. FDA will determine at the time of publication of the final MOU how long it will allow States to consider whether to sign the MOU before FDA begins to enforce the 5 percent limit in those States that have not signed an MOU.

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

## VIII. Electronic Access

Persons with access to the Internet may obtain the draft standard MOU at *http://www.regulations.gov.*

Dated: February 12, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–03420 Filed 2–18–15; 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; Draft Guidance for Industry; Availability

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is announcing the availability of a draft guidance for industry entitled ''Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application.'' This draft guidance describes the conditions under which FDA does not intend to take action against a state-licensed pharmacy, a Federal facility, or outsourcing facility that mixes, dilutes, or repackages certain biological products without obtaining an approved biologics license application (BLA).

**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 May 20, 2015.

**ADDRESSES:** 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 guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Leah Christl, Center for Drugs Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6426, Silver Spring, MD 20903, 301–796–0869; 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 draft guidance for industry entitled ''Mixing, Diluting, or Repackaging of Biological Products Outside the Scope of an Approved Biologics License Application.'' Certain licensed biological products may need to 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 (21 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) 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 without obtaining an approved BLA.

Elsewhere in this issue of the **Federal Register**, the Agency is making available for comment a draft guidance entitled ''Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities.'' When these two guidances become final, they will address and clarify the Agency's policy regarding hospital pharmacies repackaging and safely transferring repackaged drug, including biological products, to other hospitals within the same health system during a drug shortage. Therefore, under section 506F(d) of the FD&C Act (21 U.S.C. 356f(d), when FDA issues these as final guidances, section 506F will no longer apply.

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. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

## III. 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.

*Title:* Draft Guidance for Industry: Mixing, Diluting, or Repackaging of Biological Products Outside the Scope of an Approved Biologics License Application.

*Description:* The draft guidance describes FDA's policy with respect to the mixing, diluting, and repackaging of certain types of biological products that have been licensed under section 351 of the PHS Act when such activities are not within the scope of the product's approved BLA as described in the approved labeling for the product. The 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) and where specified, section 501(a)(2)(B) of the FD&C Act, when a state-licensed pharmacy, a Federal facility, or an outsourcing facility mixes, dilutes, or repackages certain biological products without obtaining an approved BLA.

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

One 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 product was mixed or 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 ingredients are listed because they were listed on the original product, the label of the mixed, diluted, or repackaged product should include any additional ingredients that appear in the mixed, diluted, or repackaged product.

Another condition in the draft guidance is that, if the immediate product label is too small or the mixed, diluted, or repackaged product is otherwise unable to accommodate a label with sufficient space 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).

In addition, the draft guidance describes the conditions that the container label 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. Another condition in the draft guidance is that each mixed, diluted, or repackaged biological product is also accompanied by a copy of the prescribing information that accompanied the original licensed biological product that was mixed, diluted, or repackaged.

We estimate that annually a total of approximately five registered 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 25 labels that include the information set forth in section III.B of the draft guidance (including directions for use) (''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 combined to provide subcutaneous immunotherapy to an individual patient) by a physician, state-licensed pharmacy, a Federal facility, or outsourcing facility. Under the draft guidance, 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;
- 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 of the prescription set;
- storage and handling instructions for the prescription set; and
- the statement ''Not for resale''.

In addition, under the draft guidance, 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 is also accompanied by instructions for use and the FDA approved package insert for each allergenic extract.

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 the statement *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 also estimate that a total of approximately five outsourcing facilities (''Number of Respondents'' in table 2, row 2) will each design, test, and produce the instructions for use and a copy of prescribing information, as set forth in section III.C of the draft guidance, for approximately 300 prescription sets (''Frequency per Disclosure'' in table 2, row 2) for a total of 1500 disclosures (total disclosures'' in table 2, row 2), which we estimate will take approximately 1 hour for each prescription set (''Hours per Disclosure'' in table 2, row 2). The provision to include *http://www.fda.gov/medwatch* and 1–800–FDA–1088 is not included in this burden estimate because they are 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)).

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

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

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

| Biological product mixing, diluting, and repackaging | Number of respondents | Frequency per disclosure | Total disclosures | Hours per disclosure | Total hours |
|---|---|---|---|---|---|
| Designing, testing, and producing the label, container, packages, and/or outer containers for each mixed, diluted, or repackaged biological product | 5 | 5 | 25 | 0.5 | 12.5 |
| Prescribing information labeling accompanying each mixed, diluted, or repackaged drug product | 5 | 5 | 25 | 1 | 25 |
| Total | | | | | 37.5 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
*(30 minutes)

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

| Preparation of prescription sets | Number of respondents | Frequency per disclosure | Total disclosures | Hours per disclosure | Total hours |
|---|---|---|---|---|---|
| Designing, testing, and producing each label on immediate containers, packages, and/or outer containers | 5 | 300 | 1500 | 0.5 | 750 |
| Including instructions for use labeling and the original package insert(s) for each prescription set | 5 | 300 | 1500 | 1 | 1500 |
| Total | | | | | 2250 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
*(30 minutes)

The draft guidance also references registration, product reporting, current good manufacturing practice (CGMP) requirements, and the payment of certain fees by human drug compounding outsourcing facilities. In the **Federal Register** of December 4, 2013 (78 FR 72899), FDA estimated the burden resulting from outsourcing facility registration. In the **Federal Register** of December 4, 2013 (78 FR 72897), FDA estimated the burden resulting from outsourcing facility interim product reporting. In the **Federal Register** of April 1, 2014 (79 FR 18297), FDA estimated the burden resulting from the payment of certain fees by outsourcing facilities. 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 *http://www.regulations.gov.*

Dated: February 11, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–03418 Filed 2–18–15; 8:45 am]

**BILLING CODE 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; Draft 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 draft 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 the Federal Food, Drug, and Cosmetic Act (the FD&C Act), when a state-licensed pharmacy, a Federal facility, or an outsourcing facility repackages human drug products.

When this guidance becomes final, the Agency may also consider withdrawing or revising other guidance documents that address human drug repackaging, including section 446.100 of the Compliance Program Guidance (CPG) Manual, entitled ''Regulatory Action Regarding Approved New Drugs and Antibiotic Drug Products Subjected to Additional Processing or other Manipulations,'' which was issued in January 1991, and section 460.100 of the CPG Manual, entitled ''Hospital Pharmacies—Status as Drug Manufacturer,'' which was issued in October 1980.

**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 May 20, 2015.

**ADDRESSES:** 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. 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.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Gail Bormel, Food and Drug Administration, 10001 New Hampshire Ave., Silver Spring, MD 20903, 301–796–3110.

**SUPPLEMENTARY INFORMATION:**

## I. Announcement of Draft Guidance

FDA is announcing the availability of a draft guidance for industry entitled