Drug, and Cosmetic Act (the FD&C Act), as added by the Drug Quality and Security Act (DQSA), of the regulatory implications of registration as an outsourcing facility.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by May 20, 2015.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, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993. 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: Sara Rothman, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–3110.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Guidance for Entities Considering Whether to Register as Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' On November 27, 2013, President Obama signed the DQSA (Pub. L. 113–54) into law. The DQSA added a new section 503B to the FD&C Act that created a category of entities called ''outsourcing facilities.'' Section 503B(d)(4) of the FD&C Act (21 U.S.C. 353b(d)(4)) defines an outsourcing facility, in part, as a facility that complies with all of the requirements of section 503B, including registering with FDA as an outsourcing facility and paying associated fees. If the conditions outlined in section 503B(a) of the FD&C Act are satisfied, a drug compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility is exempt from certain sections of the FD&C Act, including section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use) and section 505 (21 U.S.C. 355) (concerning the approval of human drug products under new drug applications (NDAs) or abbreviated new drug applications (ANDAs)). Drugs compounded in outsourcing facilities are not exempt from the requirements of section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice for drugs).

FDA has received questions about whether entities engaged in various types of activities (*e.g.,* a facility that is compounding only non-sterile drugs or only repackaging biological products) should register as an outsourcing facility. Because entities that register as outsourcing facilities in fiscal year 2015 (beginning October 1, 2014) must pay a registration fee and FDA has determined that fees paid pursuant to sections 503B and 744K of the FD&C Act will not be refunded, FDA is issuing this guidance to answer some of these questions and to provide potential registrants additional information about the regulatory impact of registering as an outsourcing facility.

Elsewhere in this volume of the **Federal Register**, FDA is announcing the availability of separate FDA guidance documents on (1) mixing, diluting, or repackaging biological products outside the scope of an approved biologics license application, and (2) repackaging certain human drug products by pharmacies and outsourcing facilities. These guidance documents describe FDA's compliance policies with respect to biological products that are mixed, diluted, or repackaged outside the scope of an approved biologics license application and repackaged human drugs.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on registering as an outsourcing facility under section 503B of the FD&C Act. 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. Electronic Access

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

Dated: February 11, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–03416 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–2138]

Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a draft guidance for industry entitled ''Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' Under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), an outsourcing facility must submit adverse event reports to FDA. This guidance explains FDA's current thinking on adverse event reporting for outsourcing facilities.

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 to finalize the guidance, submit either electronic or written comments on this draft guidance by May 20, 2015. Submit either electronic or written comments concerning the collection of information proposed in the draft guidance by May 20, 2015.

ADDRESSES: 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. 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.

Submit electronic comments on the draft 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: H. Joy Sharp, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3100.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' On November 27, 2013, President Obama signed the Drug Quality and Security Act (DQSA) into law (Pub. L. 113–54). The DQSA added a new section 503B to the FD&C Act (21 U.S.C. 353b). Under section 503B(b), a compounder can register as an outsourcing facility with FDA. Section 503B(d)(4) of the FD&C Act defines an outsourcing facility, in part, as a facility that complies with all of the requirements of section 503B, including registering with FDA as an outsourcing facility and paying associated fees. If the conditions outlined in section 503B(a) of the FD&C Act are satisfied, a drug compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility is exempt from certain sections of the FD&C Act, including section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use) and section 505 (21 U.S.C. 355) (concerning the approval of human drug products under new drug applications (NDAs) or abbreviated new drug applications (ANDAs)). Drugs compounded in outsourcing facilities are not exempt from the requirements of section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice for drugs).

Under section 503B(b)(5), an outsourcing facility must submit adverse event reports to FDA in accordance with the content and format requirements established through guidance or regulation under section 310.305 of title 21, Code of Federal Regulations (or any successor regulations). This draft guidance explains how FDA intends to implement § 310.305 with respect to outsourcing facilities.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on this topic. 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

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information that they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) 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** for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

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

Under the draft guidance, registered outsourcing facilities must submit to FDA adverse event reports within 15 calendar days of receiving the information and must submit a followup report within 15 calendar days of receipt of new information about the adverse event, or as requested by FDA. Outsourcing facilities must submit the adverse event report using the existing Form FDA 3500A (which is approved by OMB control number 0910–0291) or an alternate method in accordance with § 310.305(d). A copy of the current labeling of the compounded drug product must be included. Each form should be submitted with a cover letter that includes the following heading: ''Adverse event report submitted by human drug compounding outsourcing facility (503B).''

Under § 310.305, entities subject to the regulation must maintain for 10 years the records of all adverse events required to be reported under § 310.305, including raw data and any correspondence relating to the adverse event. The outsourcing facility should also maintain records of its efforts to obtain the data elements described in the draft guidance for each adverse event report.

The total estimated reporting and recordkeeping burdens for the draft guidance are as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of reporting	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (hours)	Total hours
Submission of adverse event reports including cover letter, copy of labeling, and other information as described in the draft guidance	50	2	100	1.1	110
Total					110

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Type of recordkeeping	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (hours)	Total hours
Records of adverse events, including records of efforts to obtain the data elements for each adverse event report	50	1	50	16	800

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

III. 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 can 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.*

IV. Electronic Access

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

Dated: February 11, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–03419 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–N–1459]

Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the States and the Food and Drug Administration; New Proposed Draft; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; withdrawal.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability for public comment of a draft standard memorandum of understanding (MOU) entitled ''Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the State of [insert State] and the U.S. Food and Drug Administration.'' The draft standard MOU describes the responsibilities of the State that chooses to sign the MOU in investigating and responding to complaints related to compounded human drug products distributed outside the State and in addressing the interstate distribution of inordinate amounts of compounded human drug products.

FDA is also announcing the withdrawal of an earlier draft standard MOU entitled ''Memorandum of Understanding on Interstate Distribution of Compounded Drug Products,'' which was issued in January 1999. The January 1999 draft standard MOU is superseded by the new draft standard MOU.

DATES: FDA is withdrawing its draft standard MOU that published on January 21, 1999 (64 FR 3301), as of February 19, 2015. Submit either electronic or written comments on the new draft standard MOU by June 19, 2015. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by June 19, 2015 (see the ''Paperwork Reduction Act of 1995'' section of this document).

ADDRESSES: Submit written requests for single copies of the MOU to Edisa Gozun, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Suite 5100, Silver Spring, MD 20993–0002. Send one self-addressed label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the new draft standard MOU.

Submit electronic comments on the new draft standard MOU or on the collection of information 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: Edisa Gozun, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Suite 5100, Silver Spring, MD 20993–0002, 301–796–3110.

SUPPLEMENTARY INFORMATION:

I. Background

Section 503A of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 353a) describes the conditions that must be satisfied for drug products compounded by a licensed pharmacist or licensed physician to be exempt from the following sections of the FD&C Act: (1) Section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice (CGMP) requirements), (2) section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use), and (3) section 505 (21 U.S.C. 355) (concerning the approval of drugs under new drug applications or abbreviated new drug applications).

One of the conditions to qualify for the exemptions listed in section 503A of the FD&C Act is that (1) the drug product is compounded in a State that has entered into an MOU with FDA that addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State; or (2) if the drug product is compounded in a State that has not entered into such an MOU, the licensed pharmacist, pharmacy, or physician does not distribute, or cause to be distributed, compounded drug products out of the State in which they are compounded in quantities that exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician (see section 503A(b)(3)(B)(i) and (b)(3)(B)(ii) of the FD&C Act).

Section 503A(b)(3)(B) of the FD&C Act directs FDA to develop, in consultation with the National Association of Boards of Pharmacy (NABP), a standard MOU for use by the States in complying with section 503A(b)(3)(B)(i).

II. Previous Efforts To Develop a Standard MOU

In the **Federal Register** of January 21, 1999 (64 FR 3301), FDA announced the availability for public comment of a draft standard MOU, developed in consultation with NABP (1999 draft