Prevention and the Agency for Toxic Substances and Disease Registry.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1444]

Final Guidance; Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act; 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 guidance entitled ''Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act.'' The guidance announces the Agency's intention with regard to enforcement of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to regulate entities that compound drugs, now that the FD&C Act has been amended by the Drug Quality and Security Act (DQSA). The guidance reflects the Agency's current thinking on the issues addressed by the guidance.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Office of Communications, 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 request. 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: Marissa Chaet Brykman, 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

FDA is announcing the availability of a guidance entitled ''Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act.'' The guidance provides information to compounders of human drug products on the Agency's application of section 503A of the FD&C Act (21 U.S.C. 353a) and current enforcement policies relating to the compounding of human drug products.

Section 503A of the FD&C Act describes the conditions that must be satisfied for drug products compounded by a licensed pharmacist or licensed physician to be exempt from the following three 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); (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). All other applicable provisions of the FD&C Act remain in effect for compounded drugs, however, even if the conditions in section 503A are met.

Previously, the conditions of section 503A of the FD&C Act also included restrictions on the advertising or promotion of the compounding of any particular drug, class of drug, or type of drug, and the solicitation of prescriptions for compounded drugs. These provisions were challenged in court and held unconstitutional by the U.S. Supreme Court in 2002.[1] In 2013, the DQSA amended section 503A of the FD&C Act to remove the unconstitutional advertising, promotion, and solicitation provisions. As a result, it is necessary to explain FDA's current thinking with regard to section 503A of the FD&C Act. Several provisions of section 503A of the FD&C Act require rulemaking and consultation with a Pharmacy Compounding Advisory Committee to implement. In the guidance, FDA explains how those provisions will be applied pending those consultations and rulemaking.

Among other things, the guidance restates the provisions in section 503A of the FD&C Act that remain in effect, describes FDA's interim policies with respect to specific provisions in section 503A that require implementing regulations or other actions, and contains a non-exhaustive list of potential enforcement actions against individuals or firms that compound human drug products that do not meet the conditions of section 503A.

In the **Federal Register** of December 4, 2013 (78 FR 72901), FDA issued a document announcing the availability of the draft version of this guidance and the withdrawal of both the May 2002 Compliance Policy Guide entitled ''Pharmacy Compounding'' and the November 1998 guidance for industry entitled ''Enforcement Policy During Implementation of Section 503A of the Federal Food, Drug, and Cosmetic Act.'' The comment period on the draft guidance ended on February 3, 2014. Many of the received comments raise issues that the Agency intends to address in other policy documents and were not directly pertinent to the topics addressed in this guidance. These comments will be further considered if relevant to another policy document developed by the Agency.

FDA made the following changes in the final guidance: (1) Inserted references to the **Federal Register** documents seeking nominations for the bulk drug substances and difficult-to-compound lists under section 503A (78 FR 72841, December 4, 2013, and 78 FR 72840, December 4, 2013, respectively); (2) modified the language that discusses the time period during which the MOU will be made available to the States for their consideration and signature and the time period with regard to the enforcement of the 5 percent limit if a State chooses not to sign the MOU; and (3) made grammatical and other minor editorial changes for clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking regarding section 503A of the FD&C Act and human drug compounding. 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

[1] See *Thompson* v. *Western States Med. Ctr.,* 535 U.S. 357 (2002).

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: June 25, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0779]

Draft Guidance for Industry on Current Good Manufacturing Practice—Interim Guidance for Human Drug Compounding Outsourcing Facilities Under the Federal Food, Drug and Cosmetic Act; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Current Good Manufacturing Practice—Interim Guidance for Human Drug Compounding Outsourcing Facilities under Section 503B of the FD&C Act.'' This draft guidance describes FDA's current expectations regarding compliance with current good manufacturing practice (CGMP) requirements for facilities that compound human drugs and register with FDA as outsourcing facilities under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), in accordance with provisions added by the Drug Quality and Security Act (DQSA). FDA is also soliciting public input on specific potential alternative approaches regarding certain CGMP requirements. These potential approaches are explained in detail in the draft guidance.

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 September 2, 2014.

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, 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 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: Brian Hasselbalch, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4364, Silver Spring, MD 20993–0002, 301–796–3279.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Current Good Manufacturing Practice-Interim Guidance for Human Drug Compounding Outsourcing Facilities under Section 503B of the FD&C Act.'' On November 27, 2013, President Obama signed the DQSA (Public Law 113–54), which added section 503B to the FD&C Act (21 U.S.C. 353b). Under section 503B(b) of the FD&C Act, a compounder can register as an outsourcing facility with FDA. Drug products compounded in a registered outsourcing facility can qualify for exemptions from the FDA approval requirements in section 505 of the FD&C Act (21 U.S.C. 355) and the requirement to label products with adequate directions for use under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) if the requirements in section 503B are met. Outsourcing facilities will be inspected by FDA and must comply with other provisions of the FD&C Act, including CGMP requirements under section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)).

Under section 501(a)(2)(B) of the FD&C Act, a drug is deemed to be adulterated if it is not produced in accordance with CGMP. FDA's regulations regarding CGMP requirements for the preparation of drug products have been established in 21 CFR parts 210 and 211. FDA intends to issue more specific CGMP regulations for outsourcing facilities. Until final regulations are issued, this draft guidance describes FDA's expectations regarding outsourcing facilities and the CGMP requirements in parts 210 and 211 during this interim period. This draft guidance reflects FDA's intent to recognize the differences between compounding outsourcing facilities and conventional drug manufacturers, and to tailor CGMP requirements to the nature of the specific compounding operations conducted by outsourcing facilities while maintaining the minimum standards necessary to protect patients from the risks of contaminated or otherwise substandard compounded drug products. This draft guidance is only applicable to drugs compounded in accordance with section 503B of the FD&C Act.

FDA intends to focus its inspectional and enforcement efforts on those aspects of compounding operations that pose the highest risk to patient safety. In particular, the primary focus of this draft guidance is on those aspects of part 211 that relate to sterility assurance of sterile drug products and the safety of compounded drug products more generally, with respect to strength (e.g., subpotency, superpotency), and labeling or drug product mix-ups.

II. Specific Request for Comments and Information

In addition to comments on the draft guidance generally, FDA is requesting comments and related supporting information on the following specific issues: (1) alternative approaches that would enable an outsourcing facility to have confidence in the quality of incoming components from sources used by multiple outsourcing facilities without each individual outsourcing facility having to conduct periodic laboratory testing to confirm the information in the third-party supplier's certificate of analysis and (2) alternative approaches that would minimize the need for outsourcing facilities to establish an in-house laboratory while providing confidence about the accuracy of testing performed by a third party used by more than one outsourcing facility. FDA has described these potential alternative approaches in the draft guidance and is seeking public comment on these and any other alternative approaches.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will