4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-1444]

Draft Guidance; Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act; Withdrawal of Guidances

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SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a draft guidance entitled "Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act". The draft guidance announces the Agency's intention with regard to enforcement of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to regulate entities that compound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. When final, the guidance will reflect the Agency's current thinking on the issues addressed by the guidance.

The Agency is also announcing the withdrawal of a guidance entitled, "Enforcement Policy During Implementation of Section 503A of the Federal Food, Drug, and Cosmetic Act," which was issued in November 1998, and the withdrawal of CPG Section 460.200 of the Compliance Program Guidance (CPG) Manual entitled, "Pharmacy Compounding," which was issued in May 2002. These guidances are being withdrawn because they are no longer consistent with the Agency's current thinking on the issues they address.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on the draft guidance before it begins work on

the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Compliance Policy, Office of Enforcement, Food and Drug Administration, rm. 4025, 12420 Parklawn Dr., Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance.

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I. Announcement of Draft Guidance

FDA is announcing the availability of a draft guidance entitled "Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act." The draft guidance provides information to compounders of human drug products and to FDA staff 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.

The conditions of section 503A of the FD&C Act 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 struck down as unconstitutional by the U.S. Supreme Court in 2002.[1] Now that section 503A has been amended by the Drug Quality and Security Act to remove the unconstitutional advertising, promotion, and solicitation provisions, it is necessary to explain FDA's current thinking with regard to section 503A. Several provisions of section 503A require rulemaking and consultation with a Pharmacy Compounding Advisory Committee to implement. In the draft guidance, we explain how those provisions will be applied pending those consultations and rulemaking.

Among other things, the draft guidance restates the provisions in section 503A 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.

FDA is issuing the draft guidance as level 1 draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA'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

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

bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Withdrawal of 1998 Guidance and 2002 CPG

In a notice published in the Federal Register of November 23, 1998 (63 FR 64723), FDA announced the availability of a guidance entitled "Enforcement Policy During Implementation of Section 503A of the Federal Food, Drug, and Cosmetic Act," which is now being withdrawn. In a notice published in the Federal Register of June 7, 2002 (67 FR 39409), FDA announced the availability of CPG Section 460.200 of the Compliance Program Guidance Manual entitled "Pharmacy Compounding," which is also now being withdrawn. These two documents are being withdrawn because they are no longer consistent with FDA's current thinking on the issues they address.

III. Request for Comments

Interested persons may submit either electronic comments regarding the draft guidance to http://www.regulations.gov or written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, or by FAX: 301-827-6870. It is only necessary to send one set of comments. Identify comments with the docket number found in the 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.

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: November 27, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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