

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled “Civil Money Penalties for Tobacco Retailers: Responses to Frequently Asked Questions.” This guidance provides information in response to questions that FDA has received regarding the issuance of civil money penalties for violations of regulations issued under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) relating to tobacco products in retail outlets.

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

**ADDRESSES:** Submit written requests for single copies of the guidance document entitled “Civil Money Penalties for Tobacco Retailers: Responses to Frequently Asked Questions” to the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on 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. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:**

Gerie Voss, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1–877–287–1373, email: [gerie.voss@fda.hhs.gov](mailto:gerie.voss@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a guidance entitled “Civil Money Penalties for Tobacco Retailers: Responses to Frequently Asked Questions.” In this guidance, FDA addresses questions regarding the issuance of civil money penalties for violations of tobacco product regulations. In the **Federal Register** of February 8, 2013 (78 FR 9396), FDA announced the availability of the draft guidance of the same title. FDA received a few comments on the draft guidance and those comments were considered as the guidance was finalized. In addition, editorial changes were made to improve clarity.

**II. Significance of Guidance**

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 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 statute and regulations.

**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 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**

An electronic version of the guidance document is available on the Internet at <http://www.regulations.gov> and <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm>.

Dated: November 27, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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**BILLING CODE 4164–01–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 February 3, 2014.

**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.<sup>1</sup> 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 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>

Dated: November 27, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013-28963 Filed 12-2-13; 11:15 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of General Medical Sciences Special Emphasis Panel; Collaborations for Macromolecular Interactions in Cells (R01).

*Date:* December 6, 2013.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* The Serrano Hotel, 405 Taylor Street, San Francisco, CA 94102.

*Contact Person:* Margaret J. Weidman, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An.18B, Bethesda, MD 20892-4874, 301-594-3663, [weidmanma@nigms.nih.gov](mailto:weidmanma@nigms.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: November 29, 2013.

**Melanie J. Gray,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center For Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material,

<sup>1</sup> See *Thompson v. Western States Med. Ctr.*, 535 U.S. 357 (2002).