

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Board on Radiation and Worker Health (ABRWH or Advisory Board), National Institute for Occupational Safety and Health (NIOSH)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), and pursuant to the requirements of 42 CFR 83.15(a), the Centers for Disease Control and Prevention (CDC), announces the following meeting of the aforementioned committee:

Board Public Meeting Time and Date (All times are Mountain Time):

8:15 a.m.–5:30 p.m., July 29, 2014

Public Comment Time and Date (All times are Mountain Time):

5:30 p.m.–6:30 p.m.*, July 29, 2014

**Please note that the public comment periods may end before the times indicated, following the last call for comments. Members of the public who wish to provide public comments should plan to attend public comment sessions at the start times listed.*

Place: Hotel On The Falls, 475 River Parkway, Idaho Falls, Idaho 83402; Phone: (208) 523-8000; Fax: (208) 529-9610. Audio Conference Call via FTS Conferencing. The USA toll-free, dial-in number is 1-866-659-0537 with a pass code of 9933701. Live Meeting CONNECTION: <https://www.livemeeting.com/cc/cdc/join?id=988QJ4&role=attend&pw=ABRWH>; Meeting ID: 988QJ4; Entry Code: ABRWH

Status: Open to the public, limited only by the space available. The meeting space accommodates approximately 100 people.

Background: The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines which have been promulgated by the Department of Health and Human Services (HHS) as a final rule, advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule, advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the

compensation program, and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC).

In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to the CDC. NIOSH implements this responsibility for CDC. The charter was issued on August 3, 2001, renewed at appropriate intervals, and will expire on August 3, 2015.

Purpose: This Advisory Board is charged with a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and c) upon request by the Secretary, HHS, advising the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class.

Matters for Discussion: The agenda for the Advisory Board meeting includes: NIOSH Program Update; Department of Labor Program Update; Department of Energy Program Update; SEC petitions for: General Atomics (La Jolla, CA), and Simonds Saw and Steel (Lockport, NY); SEC Issues Work Group Report on “Sufficient Accuracy”/Co-Worker Dose Modeling; Worker Outreach Work Group Report; SEC Petitions Update; and Board Work Session.

The agenda is subject to change as priorities dictate.

In the event an individual cannot attend, written comments may be submitted in accordance with the redaction policy provided below. Any written comments received will be provided at the meeting and should be submitted to the contact person below well in advance of the meeting.

Policy on Redaction of Board Meeting Transcripts (Public Comment): (1) If a person making a comment gives his or her personal information, no attempt will be made to redact the name; however, NIOSH will redact other personally identifiable information, such as contact information, social security numbers, case numbers, etc., of the commenter. (2) If an individual in making a statement reveals personal information (e.g., medical or employment information) about themselves that information will not usually be redacted. The NIOSH Freedom of Information Act (FOIA)

coordinator will, however, review such revelations in accordance with the Federal Advisory Committee Act and if deemed appropriate, will redact such information. (3) If a commenter reveals personal information concerning a living third party, that information will be reviewed by the NIOSH FOIA coordinator, and upon determination, if deemed appropriated, such information will be redacted, unless the disclosure is made by the third party's authorized representative under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) program. (4) In general, information concerning a deceased third party may be disclosed; however, such information will be redacted if (a) the disclosure is made by an individual other than the survivor claimant, a parent, spouse, or child, or the authorized representative of the deceased third party; (b) if it is unclear whether the third party is living or deceased; or (c) the information is unrelated or irrelevant to the purpose of the disclosure. (5) The Board will take reasonable steps to ensure that individuals making public comment are aware of the fact that their comments (including their name, if provided) will appear in a transcript of the meeting posted on a public Web site. Such reasonable steps include: (a) A statement read at the start of each public comment period stating that transcripts will be posted and names of speakers will not be redacted; (b) A printed copy of the statement mentioned in (a) above will be displayed on the table where individuals sign up to make public comments; (c) A statement such as outlined in (a) above will also appear with the agenda for a Board Meeting when it is posted on the NIOSH Web site; (d) A statement such as in (a) above will appear in the **Federal Register** Notice that announces Board and Subcommittee meetings.

Contact Person For More Information: Theodore Katz, Designated Federal Officer, NIOSH, CDC, 1600 Clifton Road NE., MS E-20, Atlanta, Georgia 30333, telephone: (513) 533-6800, toll free: 1-800-CDC-INFO, email: dcas@cdc.gov.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and

Prevention and the Agency for Toxic Substances and Disease Registry.

Gary Johnson,

Acting Director, Management Analysis and Services Office Centers for Disease Control and Prevention.

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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).