

503A were challenged by seven compounding pharmacies as being impermissible regulation of commercial speech. The U.S. District Court for the District of Nevada ruled in the plaintiffs' favor. The Government appealed to the U.S. Court of Appeals for the Ninth Circuit. On February 6, 2001, the Court of Appeals declared section 503A invalid in its entirety (*Western States Medical Center v. Shalala*, 238 F.3rd 1090 (9th Cir. 2001)). The Government petitioned for a writ of certiorari to the U.S. Supreme Court for review of the circuit court opinion. The Supreme Court granted the writ and issued its decision in the case on April 29, 2002, (*Thompson v. Western States Medical Center*, No. 01-344, April 29, 2002).

The Supreme Court affirmed the Ninth Circuit Court of Appeals decision that found section 503A of the act to be invalid in its entirety because it contained unconstitutional restrictions on commercial speech (i.e., prohibitions on soliciting prescriptions for and advertising specific compounded drugs). The Supreme Court did not rule on, and therefore left in place, the Ninth Circuit's holding that the unconstitutional restrictions on commercial speech could not be severed from the rest of section 503A of the act. Accordingly, all of section 503A is now invalid.

FDA has therefore determined that it needs to issue guidance to the compounding industry and FDA staff on what types of compounding might be subject to enforcement action under current law.

This guidance is being issued as a level 1 guidance consistent with our good guidance practices (GGPs) regulation in § 10.115 (21 CFR 10.115). It is being implemented immediately without prior public comment, under § 21 CFR 10.115(g)(2), because of the agency's urgent need to explain how, in light of the Supreme Court decision, it will exercise its enforcement discretion in regard to compounded human drugs. However, pursuant to GGPs, FDA requests comments on the guidance and will revise the document, if appropriate. Comments will be considered by the agency in the development of future policy.

This guidance represents the agency's current thinking on the enforcement of the act in regard to drug products compounded by pharmacies. 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 applicable statutes and regulations.

II. Comments

Interested persons may, at any time, submit written or electronic comments on the guidance to the Dockets Management Branch (see **ADDRESSES**). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/cder/guidance/index.htm>, <http://www.fda.gov/ora> under "Compliance References," or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: May 30, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02-14259 Filed 6-4-02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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 on Deafness and Other Communications Disorders Special Emphasis Panel, NIDCD Small Grants on communication disorders.

Date: July 24-25, 2002.

Time: July 24, 2002, 8 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Time: July 25, 2002, 8 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Stanley C. Oaks, PhD, Scientific Review Branch, Division of Extramural Research, Executive Plaza South, Room 400C, 6120 Executive Blvd., Bethesda, MD 20892-7180. 301-496-8683.

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: May 31, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02-14304 Filed 6-6-02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute on Deafness and Other Communications Disorders Special Emphasis Panel, June 19, 2002, 8 a.m. to June 19, 2002, 5 p.m., Hyatt Regency of Bethesda, MD, 20814 which was published in the Federal Register on May 22, 2002, 67 FR 36012.

The meeting will be held at the Governor's House Hotel, 1615 Rhode Island Avenue, Washington, DC to review grant applications. The meeting is closed to the public.

Dated: May 31, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02-14305 Filed 6-6-02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institutes of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Committee Act, as amended (5 U.S.C. Appendix 2), 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