

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D-0242]

Pharmacy Compounding Compliance Policy Guide; Availability

AGENCY: Food and Drug Administration, HHS

ACTION: Notice.

DMB  
Display Date 6-4-02  
Publication Date 6-7-02  
Certifier d. Hawkins

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for FDA staff and industry entitled "Sec. 460.200 Pharmacy Compounding." The document being issued with this notice provides guidance to drug compounders on how FDA intends to address pharmacy compounding as a result of a recent decision by the Supreme Court.

**DATES:** Submit written or electronic comments on the guidance at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or to the Division of Compliance Policy (HFC-230), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Fred Richman, Center for Drug Evaluation and Research (HFD-330), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301-594-0101.

**SUPPLEMENTARY INFORMATION:**

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## I. Background

On March 16, 1992, FDA issued a CPG, section 460.200 (formerly CPG 7132.16), which delineated FDA's enforcement policy on pharmacy compounding. This CPG represented FDA's policy in this area until November 1997, when the President signed into law the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115). Section 127 of FDAMA added section 503A to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 353a), which exempted compounded drug products from the requirements of sections 501(a)(2)(B) (current good manufacturing practices), 502(f)(1) (adequate directions for use), and 505 (new drug provisions) of the act (21 U.S.C. 351(a)(2)(B), 352(f)(1), and 355), provided that the compounding was conducted in accordance with and the drug products met the requirements in section 503A of the act.

In November 1998, the solicitation and advertising provisions of section 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.

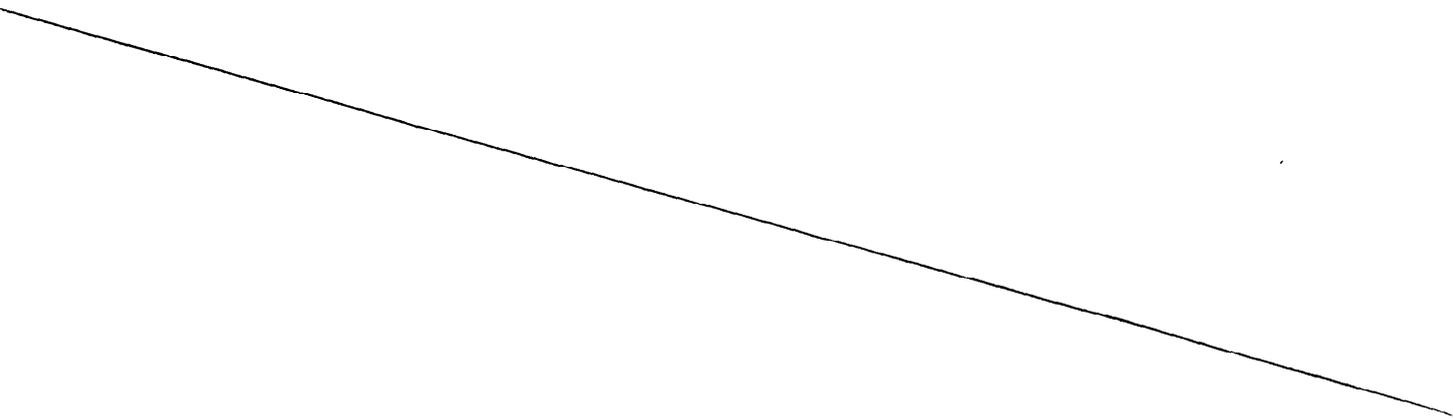
FDA has therefore determined that it needs to issue guidance to the compounding industry and FDA staff on what types of compounding might be subject to enforcement action under current law.

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: 5/30/02  
May 30, 2002



Margaret M. Dotzel  
Associate Commissioner for Policy

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