

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D-1008]

Guidance for Industry on Enforcement Policy During Implementation of 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) is announcing the availability of a guidance for industry entitled "Enforcement Policy During Implementation of Section 503A of the Federal Food, Drug, and Cosmetic Act." This guidance document provides an overview of FDA's policy on enforcement of the pharmacy compounding provisions of section 503A of the Federal Food, Drug, and Cosmetic Act (the act) during the transition to full implementation of that section, which was added by the Food and Drug Administration Modernization Act of 1997 (the Modernization Act).

DATES: Written comments on the guidance document may be submitted by (insert date 90 days after date of publication in Federal Register). General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments to the Dockets Management Branch (HFD-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests and comments should be identified with the docket number found

DMP

Display Date	11. 20 .98
Publication Date	11. 23
Certifier	C. WMS-DAY

in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Lee D. Korb, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a guidance for industry entitled “Enforcement Policy During Implementation of Section 503A of the Federal Food, Drug, and Cosmetic Act.” On November 21, 1997, the President signed the Modernization Act (Pub. L. 105-115). Section 127 of the Modernization Act, which adds section 503A to the act (21 U.S.C. 353a), clarifies the status of pharmacy compounding under Federal law. Under section 503A of the act, drug products that are compounded by a pharmacist or physician on a customized basis for an individual patient may be entitled to exemptions from three key provisions of the act: (1) The adulteration provision of section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning the good manufacturing practice requirements), (2) the misbranding provision of section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use), and (3) the new drug provision of section 505 (21 U.S.C. 355) (concerning the approval of drugs under new drug or abbreviated new drug applications).

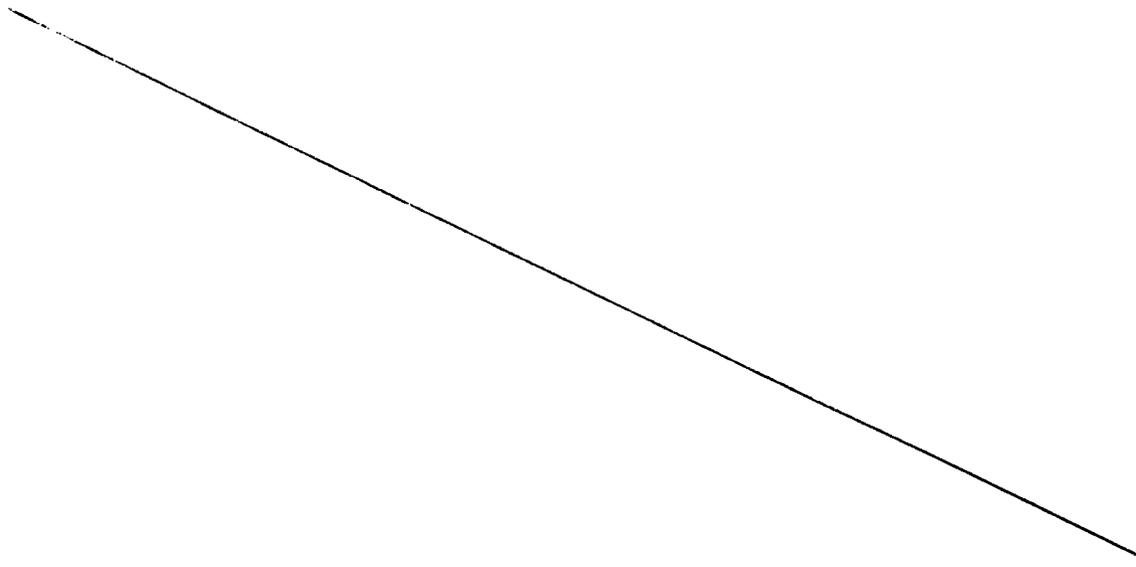
To qualify for these statutory exemptions, a compounded drug product must satisfy several requirements, some of which are to be the subject of FDA’s rulemaking or other actions. FDA is currently working on several rules and other documents necessary to implement section 503A of the act. However, section 503A of the act takes effect on November 21, 1998, and FDA will not have completed its implementation efforts by this date. This guidance document describes FDA’s policy on enforcement of section 503A of the act during the transition to full implementation of that provision.

This guidance document is being issued as a Level 1 guidance consistent with FDA's "Good Guidance Practices" (62 FR 8961, February 27, 1997). It is being implemented immediately without prior public comment because the guidance document is needed to explain to industry the agency's current policy on enforcement of section 503A of the act, which will take effect November 21, 1998. However, the agency wishes to solicit comment from the public and is providing a 90-day comment period and establishing a docket for the receipt of comments.

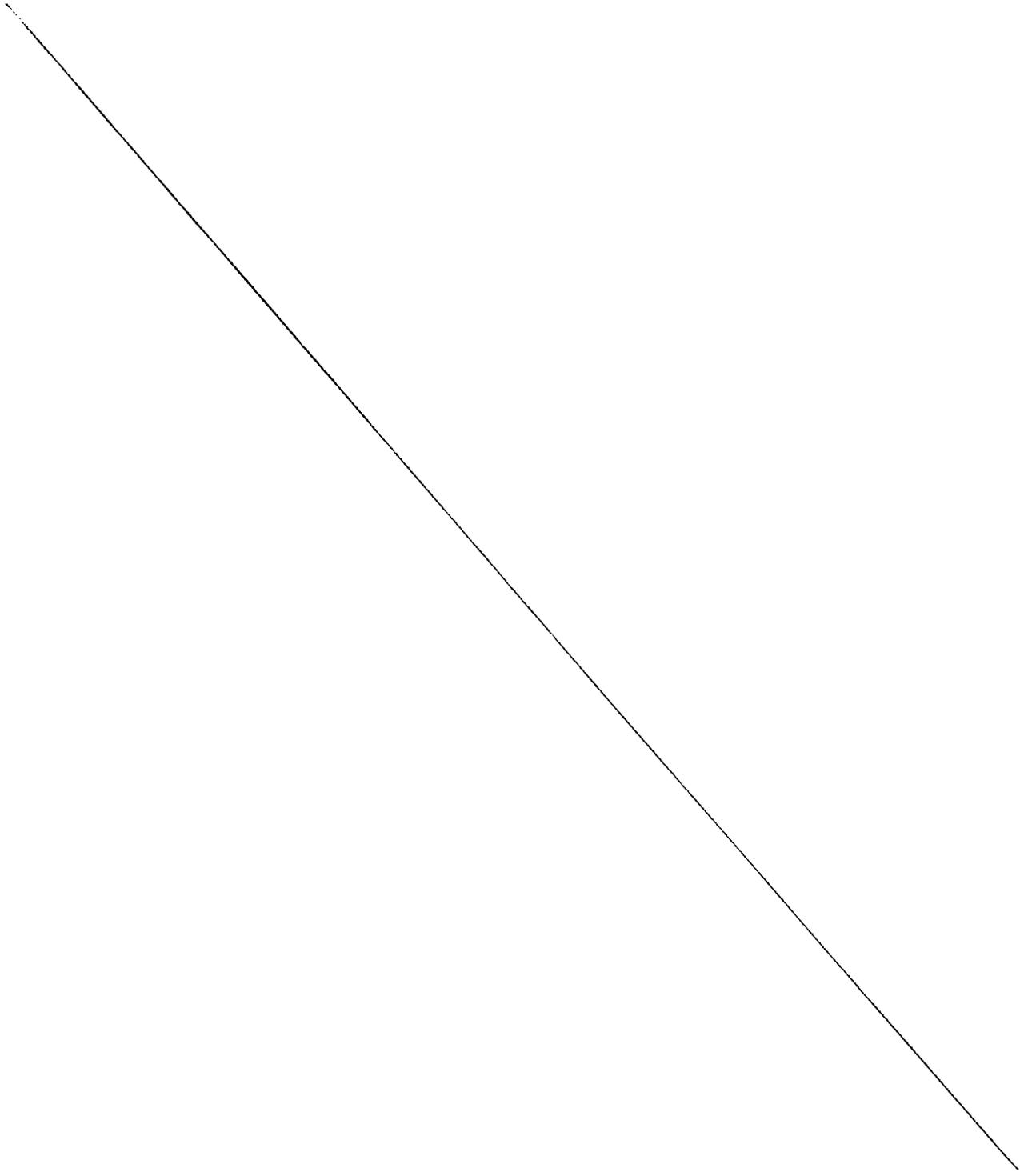
This guidance document represents the agency's current thinking on enforcement of section 503A of the act during the transition to full implementation. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

## II. Comments

Interested persons may, on or before (*insert date 90 days after date of publication in the Federal Register*), submit to the Dockets Management Branch (address above) written comments on the guidance document. 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 document and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.



**III. Electronic Access**

Persons with access to the Internet may obtain the document using the World Wide Web (WWW). For WWW access, connect to CDER at ‘<http://www.fda.gov/cder/guidance.htm>’.

Dated: 11/17/98  
November 17, 1998

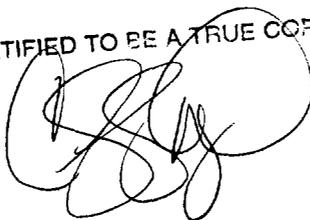
William B. Schultz

William B. Schultz  
Deputy Commissioner for Policy

[FR Doc. 98-???? Filed ??-??-98; 8:45 am]

**BILLING CODE 4160-01-F**

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

A large, stylized handwritten signature in black ink, appearing to be the signature of William B. Schultz, is written over the certification text.