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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 92 D-0077]

Compliance Policy Guide, Section 460.200 (CPG 7132.16); Rescinded

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rescission of Compliance Policy Guide (CPG), section 460.200 (formerly CPG 7132. 16) entitled “Manufacture, Distribution, and Promotion of Adulterated, Misbranded, or Unapproved New Drugs for Human Use by State-Licensed Pharmacies.” CPG 7132.16 no longer reflects current agency enforcement policy consistent with the provisions of section 127 of the Food and Drug Administration Modernization Act of 1997 (FDAMA).

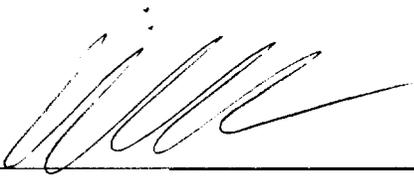
FOR FURTHER INFORMATION CONTACT: Fred Richman, Center for Drug Evaluation and Research (HFD-332), Food and Drug Administration, 7520 Standish Pi., Rockville, MD 20855-2737, 301-872-7292.

SUPPLEMENTARY INFORMATION: FDA is announcing the rescission of CPG, section 460.200 (formerly CPG 7132. 16) entitled ‘ ‘Manufacture, Distribution, and Promotion of Adulterated, Misbranded, or Unapproved New Drugs for Human Use by State-Licensed Pharmacies.’ ’ CPG 7132.16 no longer reflects current agency enforcement policy consistent with the provisions of section 127 of FDAMA.

FDAMA adds section 503A to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 353a) to describe circumstances under which compounded drugs are exempt from certain adulteration, misbranding, and new drug requirements of the act. To gain these exemptions, compounded drug products are generally prepared by a licensed pharmacist or licensed physician

for individual patients because the products are not available commercially. FDA is developing regulations and guidance on this subject.

Dated: January 4, 1999
January 4, 1999



William K. Hubbard
Associate Commissioner for Policy Coordination

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