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Display Date	5/14/99
Publication Date	5/17/99
Cost/Per	JM Wundt

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 2,3,5, 10, 12,16,20,25,50,54,56, 58,60,70,71,200,201, 202,206, 207,210,211,299,300, 310,312,314,316,320, 333,369,510,514,520, 522,524, 529,800,801,807,809, 812, and 860

[Docket No. 98N-0720]

Conforming Regulations Regarding Removal of Section 507 of the Federal Food, Drug, and Cosmetic Act; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; confirmation of effective date.

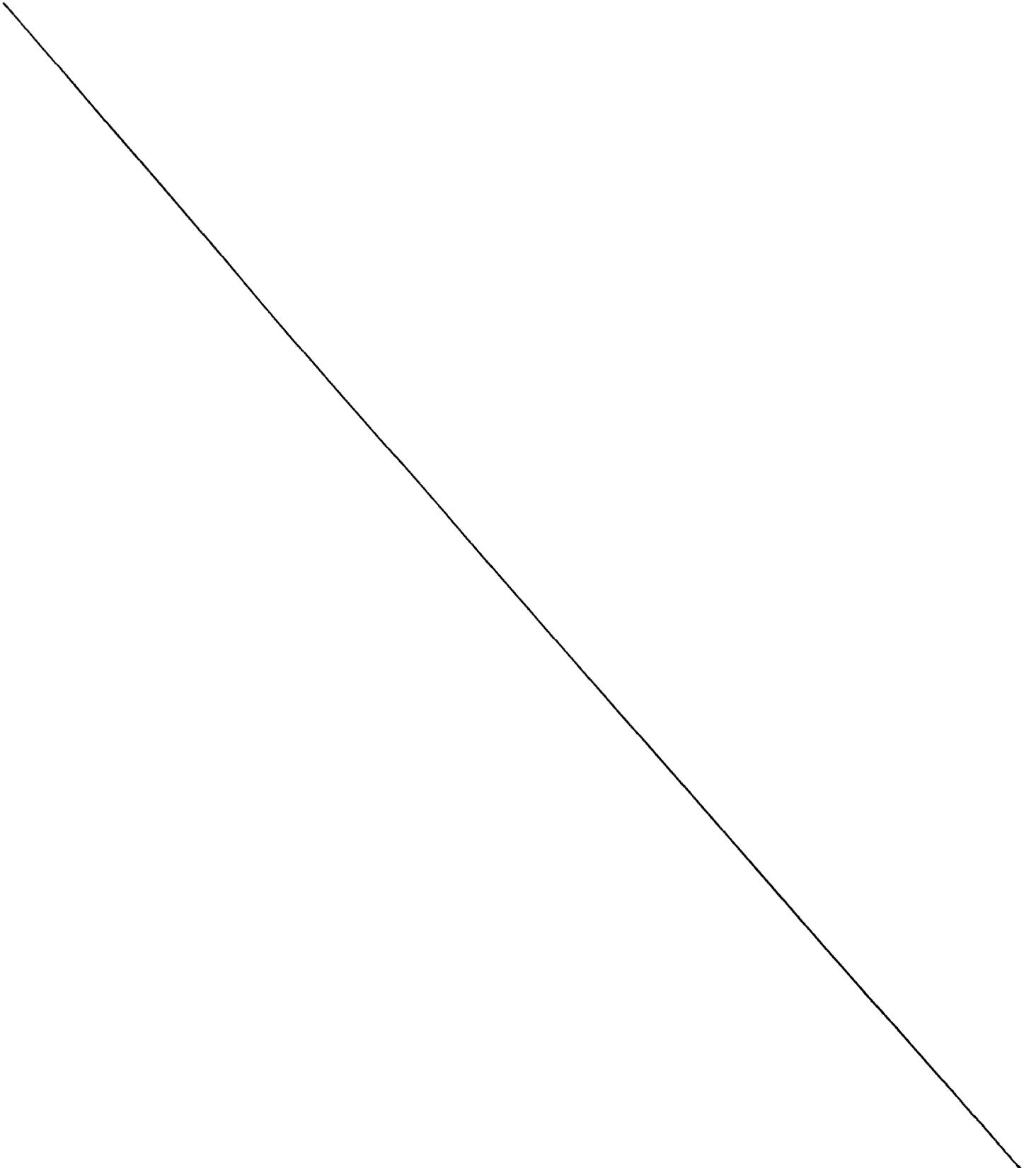
SUMMARY: The Food and Drug Administration (FDA) published in the **Federal Register** of January 5, 1999 (64 FR 396), a direct final rule. The direct final rule amended FDA's regulations by removing references to the repealed statutory provision of the Federal Food, Drug, and Cosmetic Act (the act) under which the agency certified antibiotic drugs. The direct final rule also removed references to the repealed antibiotic monograph regulations and to those regulations dealing with antibiotic applications. This document confirms the effective date of the direct final rule.

EFFECTIVE DATE: The effective date of the direct final rule published at 64 FR 396 is confirmed as May 20, 1999.

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

SUPPLEMENTARY INFORMATION: FDA solicited comments concerning the direct final rule for a 75-day period ending March 22, 1999. FDA stated that the effective date of the direct final rule

would be on May 20, 1999, 60 days after the end of the comment period, unless any significant adverse comment was submitted to FDA during the comment period. FDA did not receive any significant adverse comments.



Therefore, under the act, the FDA Modernization Act, and authority delegated to the Commissioner of Food and Drugs, notice is given that no objections were filed in response to the January 5, 1999, final rule. Accordingly, the amendments issued thereby are effective May 20, 1999.

Dated: May 10, 1999
May 10, 1999



William K. Hubbard
Associate Commissioner for
Policy Coordination

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[FR Dec. 99-???? Filed ??-??-99; 8:45 am]

BILLING CODE 4160-01-F