

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 610

[Docket No. 2005N-0355]

RIN 0910-AF20

Revocation of Status of Specific Products; Group A Streptococcus; 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) is confirming the effective date of June 2, 2006, for the direct final rule that appeared in the **Federal Register** of December 2, 2005 (70 FR 72197). The direct final rule removes the regulation applicable to the status of specific products; Group A streptococcus. FDA is removing the regulation because the existing requirement for Group A streptococcus organisms and derivatives is both obsolete and a perceived impediment to the development of Group A streptococcus vaccines. This document confirms the effective date of the direct final rule.

DATES: Effective date confirmed: June 2, 2006.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 2, 2005 (70 FR 72197), FDA solicited comments concerning the direct final rule for a 75-day period ending February 15, 2006. FDA stated that the effective date of the

direct final rule would be on June 2, 2006, 6 months after the date of publication in the **Federal Register**, unless any significant adverse comment was submitted to FDA during the comment period. FDA did not receive any significant adverse comments. Therefore, FDA is removing from the regulation 21 CFR 610.19 because this provision is obsolete and a perceived impediment to the development of Group A streptococcus vaccines.

Authority: Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act and under authority delegated to the Commissioner of Food and Drugs, the amendment issued thereby becomes effective on June 2, 2006.

Dated: April 14, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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