

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB

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21 CFR Part 314

[Docket No. 98N-0720]

Conforming Regulations Regarding Removal of Section 507 of the Federal Food, Drug, and Cosmetic Act; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for applications for FDA approval to market a new drug to correct inadvertent errors. This action is necessary to ensure the accuracies and consistency of the regulation.

DATES: This rule is effective [*insert date 5 days after date of publication in the Federal Register*].

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: In the **Federal Register** of January 5, 1999 (64 FR 396), FDA published a direct final rule that removed from the agency's regulations references to the now-repealed statutory provision of the Federal Food, Drug, and Cosmetic Act (the act) under which the agency certified antibiotic drugs (conforming regulation). Section 314.430(f) (21 CFR 314.430(f)) provides that safety and effectiveness data and information in an application may be disclosed to the public when certain events happen. Prior to the conforming regulation, § 314.430(f)(6) read: "For applications or abbreviated applications submitted under sections 505(j) and 507 of the act, when FDA sends an approval letter to the applicant".

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The conforming regulation inadvertently changed “section 505(j)” to “section 505” and failed to remove the word “applications” from the introductory clause the first time it appeared. This document corrects those errors. Publication of this document constitutes final action under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because this amendment is nonsubstantive.

List of Subjects in 21 CFR 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

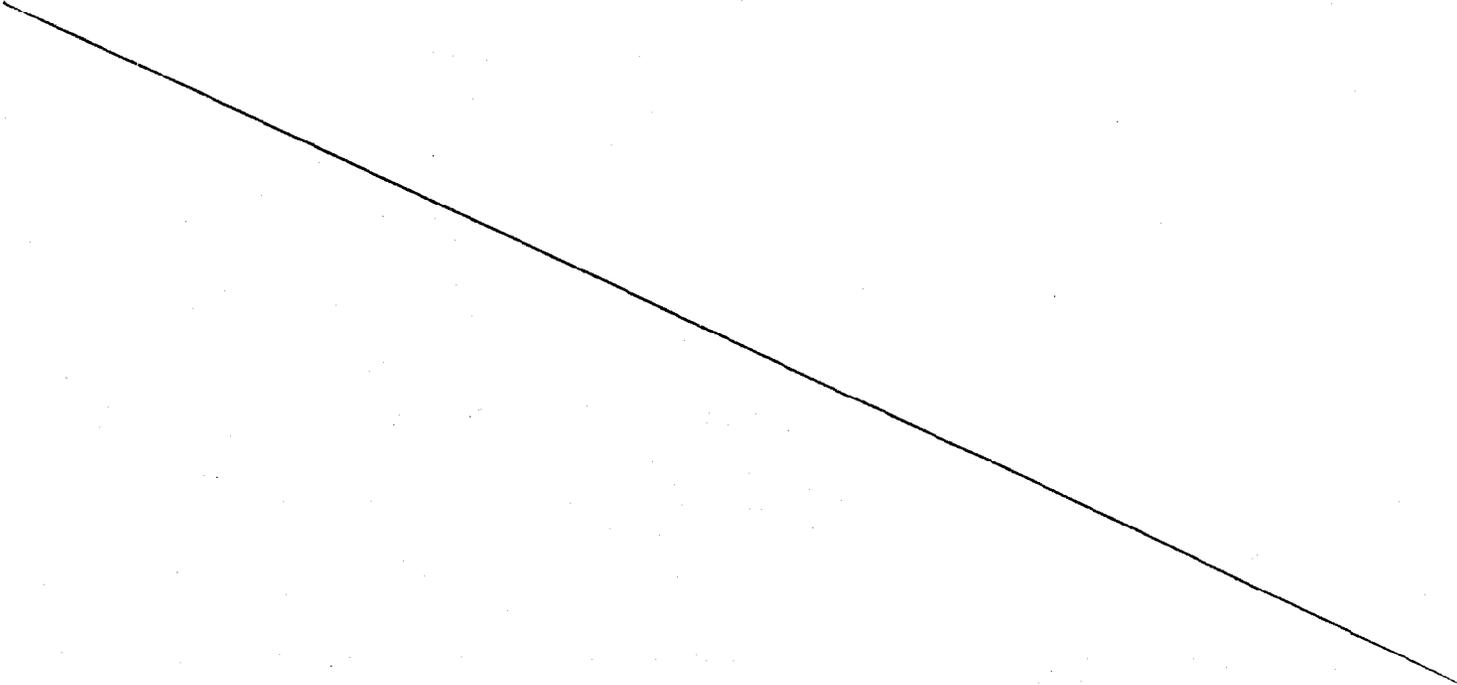
Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 314 is amended as follows:

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG

1. The authority citation for 21 CFR part 314 continues to read as follows:

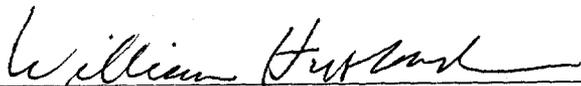
Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 371, 374, 379e.

§ 314.430 [Amended]



2. Section 314.430 *Availability for public disclosure of data and information in an application or abbreviated application* is amended in paragraph (f)(6) by removing “applications or” and by removing “505” and adding in its place “505(j)”.

Dated: January 4, 2001



William K. Hubbard,
Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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