

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 314

[Docket No. 200<sup>2</sup>N-0417]

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Certifier Sheep

**Application of 30-Month Stays on Approval of Abbreviated New Drug Applications and Certain New Drug Applications Containing a Certification That a Patent Claiming the Drug Is Invalid or Will Not Be Infringed; Technical Amendment**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule, technical amendment.

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**SUMMARY:** The Food and Drug Administration (FDA) is revoking certain sections of its regulation concerning 30-month stays of approval of abbreviated new drug applications (ANDAs) and certain new drug applications (NDAs) that contain a certification that a patent claiming the drug is invalid or will not be infringed. This action is taken in response to the passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 signed December 8, 2003. Title XI, Access to Affordable Pharmaceuticals, contains provisions that supersede sections of the regulation. This action will result in the revocation of 21 CFR 314.52(a)(3) and 21 CFR 314.95(a)(3).

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

**FOR FURTHER INFORMATION CONTACT:** Jarilyn Dupont, Office of Policy and Planning (HF-11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3360.

**SUPPLEMENTARY INFORMATION:**

## 1. Background

In the **Federal Register** of June 18, 2003 (68 FR 36676), we (FDA) issued a final rule that amended our patent submission and listing requirements. The final rule revised the regulations regarding the effective date of approval for ANDAs and certain other NDAs, known as 505(b)(2) applications, submitted under the Federal Food, Drug, and Cosmetic Act (the act). In certain situations, Federal law bars FDA from making the approval of certain ANDAs and 505(b)(2) applications effective for 30 months if the applicant has certified that a patent claiming the drug is invalid or will not be infringed and the patent owner or NDA holder then sues the applicant for patent infringement. The final rule stated that there was only one opportunity for a 30-month stay of the approval date of each ANDA and 505(b)(2) application. The final rule also clarified the types of patents that must and must not be submitted to FDA and revised the declaration that NDA applicants must submit to FDA regarding patents to help ensure that NDA applicants submit only appropriate patents. The final rule became effective on August 18, 2003.

On December 8, 2003, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173) was signed into law. Title XI, Access to Affordable Pharmaceuticals, subtitle A, section 1101 (Public Law 108–173) contains provisions that supersede sections of the regulation issued in the June 18, 2003, final rule (68 FR 36676). The new statutory provisions address the effective date of approval for certain ANDAs and 505(b)(2) applications and prohibit approval for 30 months if the applicant has certified that a patent claiming the drug is invalid or will not be infringed, and the patent owner or NDA holder then sues the applicant for patent infringement. The effective date of these provisions was made retroactive to August 18, 2003.

The new statutory provisions address the applicability of 30-month stays in approval of certain ANDAs and 505(b)(2) applications in a different manner than our final rule, which was issued under statutory language now superseded.

Therefore, certain regulations issued in the final rule published on June 18, 2003 (68 FR 36676) are superseded by the new statutory provisions. The affected sections of the regulation are 21 CFR 314.52(a)(3) and 21 CFR 314.95(a)(3) that stay the effective date of approval for certain ANDAs and 505(b)(2) applications for 30 months in certain situations.

In accordance with the new statutory provisions, we are revoking the applicable sections of the regulation. Publication of this document constitutes final action under the Administrative Procedure Act (5 U.S.C. 553(b)(3)(B)).

#### **List of Subjects in 21 CFR Part 314**

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

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs, 21 CFR 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:

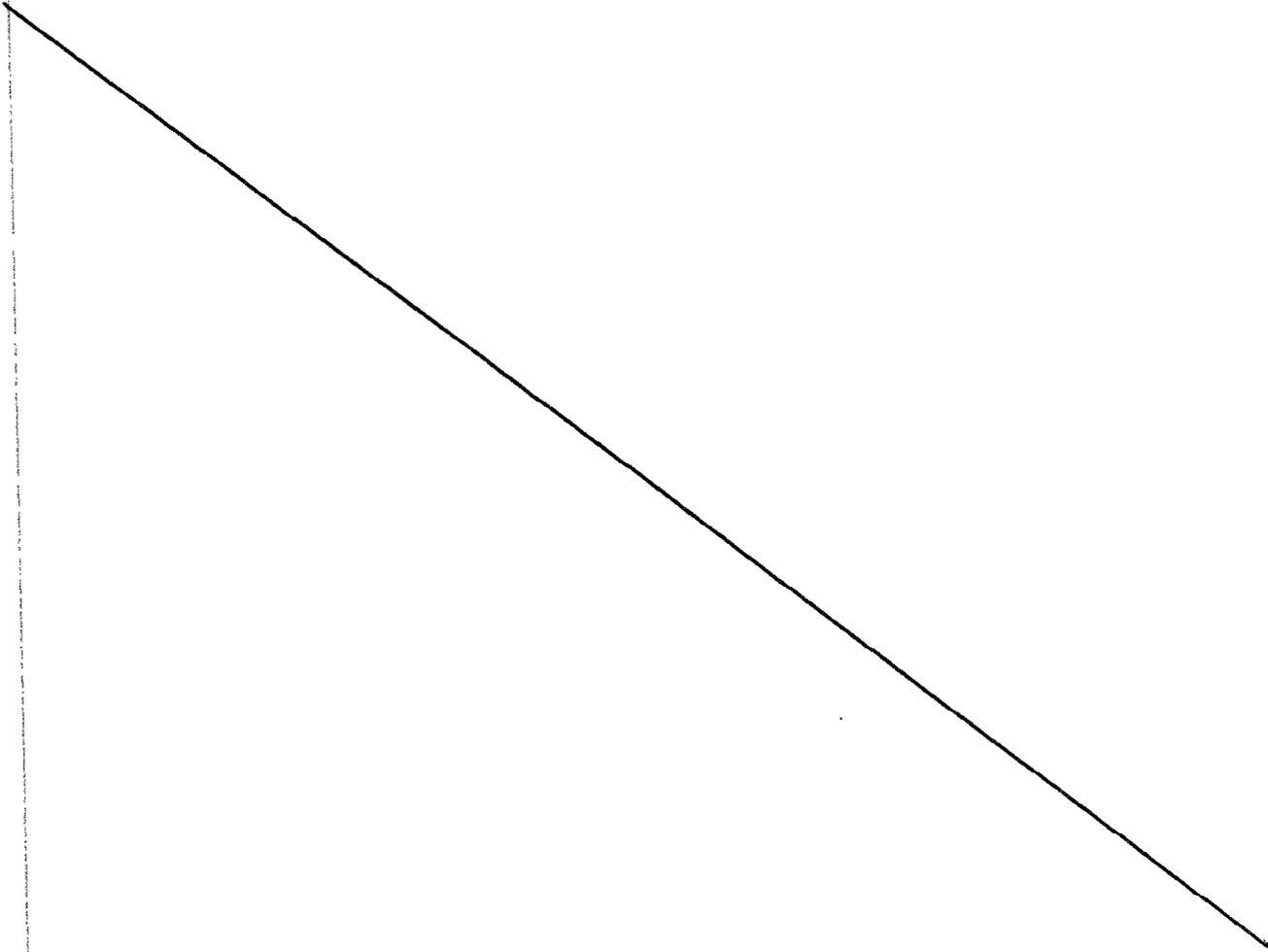
**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 355, 355a, 356, 356a, 356b, 356c, 371, 374, 379e.

**§314.52 [Amended]**

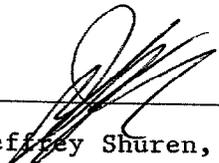
■ 2. Section 314.52 is amended by removing paragraph (a)(3) and redesignating paragraph (a)(4) as paragraph (a)(3).

**§314.95 [Amended]**

■ 3. Section 314.95 is amended by removing paragraph (a)(3) and redesignating paragraph (a)(4) as paragraph (a)(3) .



Dated: 3/1/04  
March 1, 2004.

  
Jeffrey Shuren,  
Assistant Commissioner for Policy.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

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