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Food and Drug Administration

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Certifier A. Corbin

[Docket No. 85N-0214]

**180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications**

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

**ACTION:** Proposed rule; withdrawal.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the withdrawal of a proposed rule published in the **Federal Register** of August 6, 1999 (64 FR 42873) (the August 1999 proposed rule). FDA proposed to amend its regulations governing 180-day exclusivity and the timing of certain abbreviated new drug application (ANDA) approvals under the Federal Food, Drug, and Cosmetic Act (the act). The proposed amendments to the regulations were made in response to court decisions that affected the agency's previous interpretation of relevant provisions of the act. Since the proposed rule was published, there have been additional court decisions that address FDA's interpretation of the act, including the interpretation described in portions of the proposed rule. In light of these decisions, FDA is withdrawing the August 1999 proposed rule and will reevaluate its interpretation of the act. FDA will continue to regulate directly from the statute and applicable regulations and make regulatory decisions on an issue-by-issue basis.

**DATES:** The proposed rule is withdrawn [*insert date of publication in the Federal Register*].

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

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of August 6, 1999 (64 FR 42873), FDA proposed to amend its regulations governing 180-day generic drug exclusivity under the act. The August 1999 proposed rule was an effort to clarify existing eligibility requirements for 180-day generic drug exclusivity and to describe new eligibility requirements for ANDA sponsors. The August 1999 proposed rule described a number of challenges to FDA's previous interpretations of relevant statutory provisions and proposed a new approach to implementing 180-day generic drug exclusivity. The publication of the proposed amendments was FDA's response to then-recent court decisions affecting portions of its regulations. (See *Mova Pharmaceutical Corp. v. Shalala*, 140 F.3d 1060 (D.C. Cir. 1998), and *Granutec, Inc. v. Shalala*, 139 F.3d 889, 1998 WL 153410 (4th Cir. Apr. 3, 1998)).

The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) (the Hatch-Waxman Amendments) created section 505(j) of the act (21 U.S.C. 355(j)). The ANDA approval program established by section 505(j) of the act permits a generic version of a previously approved innovator drug to be approved without submission of a full new drug application (NDA). An ANDA references a previously approved drug product (the "listed drug") and relies on the agency's prior finding of safety and effectiveness for that drug product.

Applicants seeking approval for an NDA must include in their NDA information about patents for the drug that is the subject of the NDA. FDA publishes this patent information as part of the agency's publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (the Orange Book).

Under section 505(j)(2)(A)(vii) of the act, generic drug applicants must include in an ANDA a patent certification for each patent listed in the Orange Book for the listed drug. The applicant must certify to one of the following for each listed patent: (1) That no patent information on the listed drug has been submitted to FDA; (2) that such patent has expired; (3) the date on which such patent will expire; or (4) that such patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the drug product for which the ANDA is submitted. These certifications are referred to as "paragraph I," "paragraph II," "paragraph III," and "paragraph IV" certifications, respectively. The ANDA applicant must also provide notice of a paragraph IV certification to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA refers.

Section 505(j)(5)(B)(iv) of the act provides an incentive for ANDA applicants to file paragraph IV certifications challenging patents that may be invalid, unenforceable, or not infringed by the drug product that is the subject of the ANDA. In certain circumstances, the first ANDA applicant with a paragraph IV certification is granted 180-day exclusivity. The 180-day exclusivity gives the first ANDA applicant protection from market competition by subsequent generic versions of the same drug product for a 180-day period from either the date the first ANDA applicant begins commercially marketing

its drug product or from the date of a court decision holding the patent that is the subject of the paragraph IV certification invalid, unenforceable, or not infringed.

In 1994, FDA issued its final rule implementing the patent and marketing exclusivity provisions of the Hatch-Waxman Amendments. The requirements for 180-day exclusivity are contained in § 314.107(c)(1) (21 CFR 314.107(c)(1)).

In 1998, two appellate courts found that FDA's interpretation of section 505(j)(5)(B)(iv) of the act as expressed in § 314.107(c)(1) was not supported by the act (*Mova*, 140 F.3d at 1077; *Granutec*, 139 F.3d at 889). The *Mova* and *Granutec* courts concluded that the "successful defense" requirement imposed by § 314.107(c)(1) which required an ANDA applicant to be sued for patent infringement and to win before it could qualify for 180-day exclusivity was invalid. They held that 180 days of marketing exclusivity should be granted to the first ANDA applicant that files a paragraph IV certification, regardless of whether the applicant is subsequently sued for patent infringement.

Shortly after these decisions, the agency published a guidance for industry entitled "180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act" (June 1998) (63 FR 37890, July 14, 1998), detailing its new approach to 180-day exclusivity in response to the *Mova* and *Granutec* court decisions. The agency also published an interim rule revoking the "successful defense" requirement of § 314.107(c)(1) (63 FR 59710, November 5, 1998). Since that time, the agency has regulated directly from the statute on issues not specifically addressed by the remaining regulations governing 180-day exclusivity.

In the August 1999 proposed rule, the agency described a new approach to implementing the 180-day generic drug exclusivity consistent with the act.

The August 1999 proposed rule addressed the issues resulting from the *Mova* and *Granotec* court decisions and responded to other 180-day exclusivity issues not currently addressed by the regulations.

Since publication of the August 1999 proposed rule, there has been extensive litigation of issues relating to ANDA approvals and 180-day exclusivity. Among these litigated issues was whether 180-day exclusivity would begin to run with the first district or other court decision finding the patent invalid, unenforceable, or not infringed or with a final court decision from which no appeal has been or can be taken.

FDA's interpretation of the words "the court" contained in section 505(j)(5)(B)(iii) of the act was initially challenged and reviewed by the court in *TorPharm, Inc. v. Shalala*, No. 97-1925, 1997 U.S. Dist. LEXIS 21983 (D.D.C. Sep. 15, 1997), *appeal withdrawn and remanded*, 1998 U.S. App. LEXIS 4681 (D.C. Cir. Feb. 5, 1998); *vacated* No. 97-1925 (D.D.C. Apr. 9, 1998). This provision of the act governs the approval of ANDAs when the NDA holder has brought a timely patent infringement action in response to the ANDA applicant's notice of filing a paragraph IV certification to a listed patent. The district court found that "the court," as stated in section 505(j)(5)(B)(iii) of the act, refers to the first court that decides that the patent is invalid or not infringed. Hence, the court found that under the act, the agency must make the ANDA approval effective on the date of the first relevant court decision, regardless of appeal status.

In another case decided after the proposed rule was published, the agency's interpretation of the phrase "a decision of a court" contained in section 505(j)(5)(B)(iv) of the act was successfully challenged in *Mylan Pharmaceuticals, Inc. v. Shalala*, 81 F. Supp.2d 30 (D.D.C. Jan. 4, 2000) (*Mylan*

D). Section 505(j)(5)(B)(iv) of the act governs the eligibility for and timing of 180-day exclusivity. In the regulations in § 314.107 implementing this provision of the act, FDA interpreted “court” to mean the court that enters final judgment from which no appeal can be or has been taken (21 CFR 314.107(e)(1) (1999)). The *Mylan I* court found that this interpretation was not consistent with the plain language of the act, and concluded that “court” in the phrase “a decision of a court” means the first court that renders a decision finding the patent which is the subject of the certification to be invalid, unenforceable, or not infringed.

In response to the litigation and in an effort to provide guidance to the pharmaceutical industry regarding the timing of approval of ANDAs following an unsuccessful patent infringement action by the NDA holder and the start of 180-day generic drug exclusivity, the agency issued a guidance for industry entitled “Court Decisions, ANDA Approvals, and 180-day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act” (March 2000) (the March 2000 guidance for industry). FDA announced that it would interpret the term “court” as found in section 505(j)(5)(B)(iii)(I) and (j)(5)(B)(iv) of the act to mean the first court that renders a decision finding the patent at issue invalid, unenforceable, or not infringed. FDA also announced that it would apply the new guidance policy prospectively. In the case of a district court decision, FDA may approve the ANDA as of the date the district court enters its decision. Also, for eligible applicants, 180-day exclusivity will begin to run on that date.

After the March 2000 guidance for industry was issued, the agency’s interpretation of the meaning of “court decision” was again litigated in a consolidated case, *Mylan Pharmaceuticals, Inc. v. Henney*, 94 F.Supp.2d. 36

(D.D.C. 2000) (*Mylan II*). The court in *Mylan II* found that “a decision of a court” contained in section 505(j)(5)(B)(iv)(II) of the act means all court decisions, whether subsequently vacated, settled, appealed, or otherwise mooted. *Id.* at 54.

In the **Federal Register** of July 13, 2000 (65 FR 43233), FDA issued an interim rule to amend its regulations governing the definition of “court decision” as detailed in the March 2000 guidance for industry and consistent with the *TorPharm* and *Mylan* court decisions.

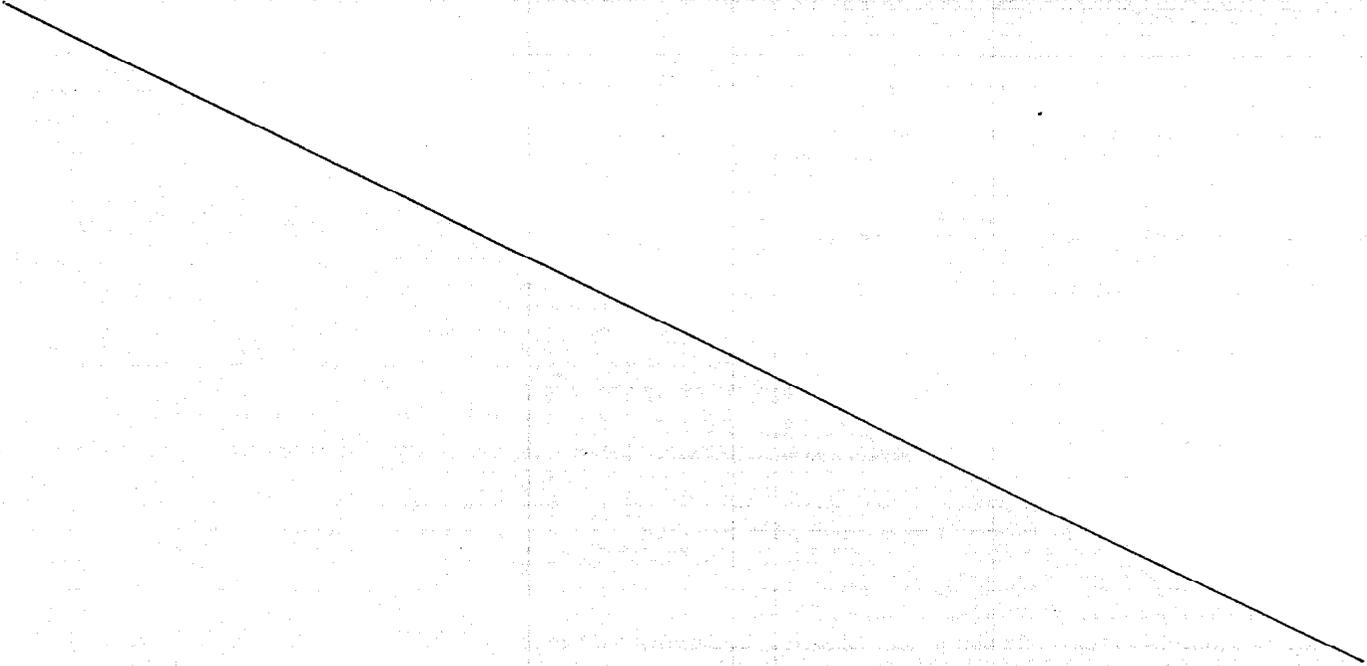
The opinion of the United States Court of Appeals for the D.C. Circuit in *Teva Pharmaceuticals, USA, Inc. v. FDA*, 182 F.3d 1003 (D.C. Cir. 1999) also rejected the agency’s interpretation of the act. The *Teva* court found that under the facts of that case, a dismissal of a declaratory judgment action for lack of subject matter jurisdiction was a court decision triggering the running of exclusivity. In *Teva*, the underlying dismissal was based on an express finding that the plaintiff lacked a reasonable apprehension of a patent infringement suit, and thus there was no case or controversy concerning infringement of the patent to give the court jurisdiction. Under these circumstances, the court held that, although the court did not opine directly on the question of infringement, the dismissal for lack of subject matter jurisdiction was a decision of a court finding the patent invalid or not infringed that triggered 180-day exclusivity. This holding was directly at odds with the approach the agency proposed in the August 1999 proposed rule to deal with dismissals of declaratory judgment actions under section 505(j)(5)(B)(iii) of the act. (See 64 FR 42873 at 42881.)

## **II. Comments on the Proposed Rule**

FDA received several comments on the August 1999 proposed rule. Comments were received from pharmaceutical companies, attorneys, trade associations, generic companies, the Federal Trade Commission, and chemical companies. The comments addressed a wide variety of issues described in the August 1999 proposed rule. Some comments favored and some opposed all or parts of the August 1999 proposed rule.

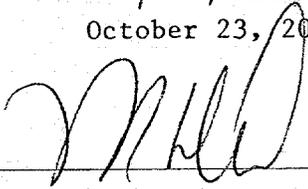
## **III. Withdrawal of the Proposed Rule**

After careful consideration of the comments on the August 1999 proposed rule and the multiple court decisions affecting the agency's interpretation of the provisions of the act relating to 180-day exclusivity and ANDA approvals, FDA has concluded that it is appropriate to withdraw the August 1999 proposed rule at this time. The agency will continue to regulate directly from



the statute and applicable FDA regulations to make 180-day exclusivity decisions on an issue-by-issue basis. The agency will also carefully evaluate possible options for future rulemaking addressing 180-day exclusivity and the timing of ANDA approvals.

Dated: 10/23/02  
October 23, 2002.



Margaret M. Dotzel,  
Associate Commissioner for Policy.

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