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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 00D-1197]

Guidance for Industry on Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of 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." The purpose of this guidance is to inform the public of FDA's application of the abbreviated new drug application (ANDA) approval provisions and 180-day generic drug exclusivity provisions of the Federal Food, Drug, and Cosmetic Act (the act) in light of recent court decisions on these issues.

DATES: Submit written comments on the guidance by [*insert date 90 days after date of publication in the Federal Register*]. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this guidance for industry are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm>. Submit written requests for single copies of the guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of 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." This guidance is being issued in response to recent litigation. The guidance is intended to provide information to the pharmaceutical industry regarding: (1) The timing of approval of ANDA's following an unsuccessful patent infringement action by the patent owner or new drug application (NDA) holder and (2) the start of 180 days of generic drug exclusivity.

FDA's interpretation of two provisions of the act have been successfully challenged in *TorPharm, Inc. v. Shalala* and *Mylan Pharmaceuticals, Inc. v. Shalala*¹. These provisions apply the concept of a court decision to the timing of certain ANDA approvals and to the start of 180-day exclusivity. There is a 30-month statutory bar to approval of an ANDA that is the subject of patent infringement litigation except if "before the expiration of such period the court decides that such patent is invalid or not infringed, the approval will be made effective on the date of the court decision" (section 505(j)(5)(B)(iii)(I) of the act (21 U.S.C. 355(j)(5)(B)(iii)(I))). Certain court decisions are also important for 180-day generic drug exclusivity. The 180-day period of exclusivity can begin on either: (1) The date of first commercial marketing, or (2) the date of a decision of a court holding the patent which is the subject of the paragraph IV certification to be invalid or not infringed, whichever is earlier (section 505(j)(5)(B)(iv) of the act). For purposes of section 505(j)(5)(B)(iii)(I) and (j)(5)(B)(iv) of the act, FDA determined that "court" means

¹ *TorPharm v. Shalala*, No. 97-1925, 1997 U.S. Dist. LEXIS 21983 (D.D.C. September 15, 1997); *appeal withdrawn and remanded*, 1998 U.S. App. LEXIS 4681 (D.C. Cir. February 5, 1998); *vacated* No. 97-1925 (D.D.C. April 9, 1998); *Mylan Pharmaceuticals, Inc. v. Shalala*, No. 99-2995, slip op. (D.D.C. January 4, 2000).

“the court that enters final judgment from which no appeal can be or has been taken” (§ 314.107(e)(1) (21 CFR 314.107(e)(1)) (1999)).

FDA’s interpretation of the term “court” has been successfully challenged in the context of both the timing of ANDA approvals and the commencement of 180-day exclusivity. These recent decisions add considerable uncertainty to FDA’s implementation of the ANDA approval and 180-day generic drug exclusivity programs. Therefore, in determining its response to the *TorPharm* and *Mylan* decisions, a primary concern for the agency has been to identify an approach that will minimize further disruption and will provide the regulated industry with reasonable guidance for making future business decisions. The government has decided not to appeal the *Mylan* decision and will follow that court’s interpretation of the statute in approving ANDA’s and calculating the commencement of 180 days of exclusivity. The agency intends to formally amend § 314.107(e) and will incorporate the *TorPharm* and *Mylan* courts’ interpretation of the statute into the final rule implementing the changes in 180-day exclusivity (64 FR 42873, August 6, 1999). FDA will implement the new interpretation of the term “court” prospectively.

FDA will 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. The new definition of “court” will be applied to approval and exclusivity determinations for all ANDA’s containing a paragraph IV certification submitted after the publication of this guidance, where the ANDA cites a reference listed drug for which no other ANDA containing a paragraph IV certification has been submitted.

This Level 1 guidance is being issued consistent with FDA’s good guidance practices (62 FR 8961, February 27, 1997). The guidance is being implemented immediately without prior public comment because the guidance is needed to explain FDA’s application of the statute in light of recent court decisions. However, the agency wishes to solicit comments from the public and is providing a 90-day comment period and establishing a docket for the receipt of comments.

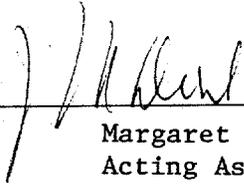
This guidance represents the agency's current thinking on section 505(j)(5)(B)(iii)(I) and (j)(5)(B)(iv) of the act. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the act.

Interested persons may submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number

found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 3/23/00

March 23, 2000



Margaret M. Dotzel
Acting Associate Commissioner for Policy

BBodo 3-24-00

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