

patent(s) are submitted on the same day or when paragraph IV certifications are submitted in an amendment or supplement on the same day.

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of this guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research (CDER), 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 Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Cecelia Parise, Center for Drug Evaluation and Research (CDER) (HFD-600), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-5845.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a guidance for industry entitled "180-Day Exclusivity When Multiple ANDAs Are Submitted on the Same Day." This guidance document provides information to sponsors and/or applicants regarding how the agency intends to determine eligibility for 180-day exclusivity under section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C 355(j)(5)(B)(iv)) when multiple ANDA applicants submit a paragraph IV certification to a listed patent on the same day and no paragraph IV certification to the patent has been submitted on any previous day.

##### **A. Statute and Regulations**

A new drug application (NDA) applicant must include in its NDA information about any patents that claim the drug product that is the subject of the NDA or the use of such drug product (section 505(b)(1) and (c)(2) of the act). FDA publishes this patent information upon approval of the NDA or a supplemental NDA in "Approved Drug Products with Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book."

An ANDA applicant must include in its ANDA a patent certification as described in section 505(j)(2)(A)(vii) of the act. The certification must make one of the following statements: (1) Such patent information has not been filed; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed by the manufacture, use, or sale of the drug product for which the ANDA is submitted. This last certification is known as a paragraph IV certification. The ANDA applicant must provide appropriate 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)(2)(B)(i) of the act (part 314 (21 CFR part 314))).

The act provides an incentive for generic drug manufacturers to file paragraph IV certifications and challenge listed patents as invalid or not infringed, thereby permitting generic drugs to reach the market more quickly. Section 505(j)(5)(B)(iv) of the act provides for a 180-day period of marketing protection for certain ANDA products as follows:

If the [ANDA] contains a [paragraph IV certification] and is for a drug for which a previous application has been submitted under this subsection continuing [sic] such a certification, the application shall be made effective not earlier than one hundred and eighty days after-

- (I) the date the Secretary receives notice from the applicant under the previous [ANDA] of the first commercial marketing of the drug under the previous [ANDA], or
- (II) the date of a decision of a court in [a patent infringement action] holding the patent which is the subject of the certification to be invalid or not infringed, whichever is earlier (emphasis added).

The statute does not further define the phrase "for which a previous application has been submitted." In its regulation at § 314.107(c), FDA uses both the terms "previously submitted" and "first" in implementing this provision of the statute. It adopts the phrase "for which one or more substantially complete abbreviated new drug applications were previously submitted" to restate the conditions under which exclusivity will apply. The regulation at § 314.107(c)(1)(i) states that exclusivity may begin to run from "[t]he date the applicant submitting the first application first commences commercial marketing of its drug product." The phrase "applicant submitting the first application" is defined in the regulation as "the applicant that submits an application that is both substantially

complete and contains a certification that the patent was invalid, unenforceable, or not infringed prior to the submission of any other application for the same listed drug that is both substantially complete and contains the same certification." (§ 314.107(c)(2)) Thus, the agency has adopted the terms "previous," "first," and "prior" to identify the ANDA eligible for exclusivity. However, the agency has not elaborated on how these terms should be applied when more than one applicant submits a paragraph IV certification to the same patent on the same day.

##### **B. 180-Day Exclusivity and Different Day Patent Certifications**

The statute and the regulations at § 314.107(c) are straightforward to apply when ANDAs, amendments, or supplements are submitted to FDA on different days. An ANDA submitted on the day before another application is submitted, when no application has been submitted on an earlier day, is clearly the "previous," the "prior" and the "first" application. To date, FDA's exclusivity decisions have involved applications or amendments submitted on different days, and thus have not required additional interpretation of the statute or regulations on this point.

Recently, FDA has had to consider how to apply the 180-day exclusivity provision when multiple challenges to the same patent are submitted on the same "first" day. After the decisions in *Mova Pharmaceuticals, Inc. v. Shalala*, 140 F.3d 1060 (D.C.Cir. 1998) and *Granutec, Inc. v. Shalala*, 46 U.S.P.Q.2d 1398 (4th Cir. 1998), the first applicant who submits a substantially complete ANDA containing a paragraph IV certification to a listed patent is eligible for 180-day generic drug exclusivity.<sup>1</sup> As noted in a 1999 citizen petition response,<sup>2</sup> many of the current regulations were adopted prior to the *Mova* decision, when the agency interpreted the statute to require that an ANDA applicant had to be sued and win its patent litigation to qualify for 180-day exclusivity. FDA's pre-*Mova* interpretation limited the number of times 180-day exclusivity was awarded because an ANDA applicant had to be first to challenge a patent and then win the patent litigation to be eligible for 180-day exclusivity. The chance of

<sup>1</sup> The regulatory history of this issue has been previously described in the June 1998 CDER guidance for industry entitled "180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendment to the Federal Food, Drug, and Cosmetic Act."

<sup>2</sup> See response to 99P-1271/PSA1 and PSA2 issued August 2, 1999.