

WATSON Pharmaceuticals, Inc.

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Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

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Re: Docket No. 01N-0103 (66 Fed. Reg. 27983);
Issues Associated With the Intersection of
Generic Drug Exclusivity and Pediatric Exclusivity

Ladies/Gentlemen:

Watson Pharmaceuticals, Inc., a manufacturer of both innovative and generic drug products, submits the following comments to the above-referenced docket.

Watson strongly urges FDA to adopt the policy, in instances when generic drug exclusivity arising from a successful paragraph IV challenge to an Orange Book patent is triggered less than 180 days before the start of (or during) a pediatric exclusivity period, that the generic drug exclusivity period runs consecutively following expiration of the pediatric exclusivity period. Having these periods run concurrently would have the unintended consequence of depriving the first-to-file ANDA applicant in this situation of the full 180 days of generic exclusivity afforded by the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act. For certain drugs, this could discourage paragraph IV challenges and thereby delays the earliest possible market entry of lower-cost drug products for consumers.

The intersection of generic and pediatric exclusivity can occur in cases of multiple Orange Book patents for the same drug, where generic exclusivity is awarded to the first ANDA applicant who successfully demonstrates the invalidity or non-infringement of one such patent in paragraph IV litigation, while pediatric exclusivity is awarded to the NDA holder for the listed drug with a valid patent in the Orange Book, and who also satisfies pediatric testing requirements for the drug.

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Consecutive running of the generic and pediatric exclusivity periods in these situations is supported by: (1) pertinent language in the generic drug exclusivity provision of the Hatch-Waxman Amendments coupled with pertinent language in the pediatric exclusivity section of the Food and Drug Modernization Act of 1997 (FDAMA); (2) accepted principles of statutory interpretation; and (3) additional legislative intent reflected in relevant letters from members of Congress to FDA.

1. Statutory Language. The generic drug exclusivity provision, enacted as part of Hatch-Waxman in 1984, is couched in terms of the time period during which approval of ANDAs subsequent to the first ANDA containing a paragraph IV certification cannot be made final. The first-to-file applicant is assured of 180 days of market exclusivity because final approval of subsequently-filed ANDAs "shall be made effective not later than one hundred and eighty days" following the date of a court decision of invalidity or non-infringement of a patent which the first-to-file applicant has successfully challenged (or the first commercial marketing by the first-to-file applicant). 21 U.S.C. §355(j)(5)(B)(iv).

The pediatric exclusivity amendment later enacted as part of FDAMA in 1997 gives force and effect to the full 180 days of the generic exclusivity period. In pertinent part, the pediatric exclusivity section states that when a listed drug NDA holder successfully prosecutes paragraph IV litigation as well as fulfills pediatric exclusivity testing requirements, "the period during which an application may not be approved under section 355 (j)(5)(B) of this title shall be extended by a period of six months after the date the patent expires." 21 U.S.C. §355A(c)(2)(B).

According to this very wording, the period when 180-day generic exclusivity begins to run under Hatch-Waxman is *simply extended* by the six-month period of pediatric exclusivity provided by FDAMA. The pediatric exclusivity *postpones the start* of the generic exclusivity period. It clearly does not truncate the generic exclusivity period. The plain statutory language of FDAMA's pediatric exclusivity section preserves the full 180 days of generic exclusivity intended by the Hatch-Waxman legislative compromise.

2. Statutory Interpretation. There is a long-standing principle applied by the courts to intersecting provisions of the FD&C Act. The most harmonious, comprehensive meaning possible must be applied, giving effect to both provisions in light of the legislative policy and purpose. See Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609 (1973) (interpreting the new drug definition and the NDA effectiveness requirement). Manifestly, this principle supports the consecutive running of the generic and pediatric exclusivity periods, so that neither the first-to-file ANDA applicant nor the listed drug NDA holder loses the privileges accorded by the respective statutory provisions.

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3. Congressional Intent. Recent letters to FDA from Senator Hatch and Congressman Waxman, architects of the generic exclusivity provision who also voted on the pediatric exclusivity provision of FDAMA, have squarely indicated a legislative intent that the latter period was not intended to shorten the former. While not part of legislative history, these communications should be taken into account by the agency in deciding this issue.

Very truly yours,

WATSON PHARMACEUTICALS, INC.



Robert C. Fursten

RCF/pbh
Enclosure