

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N-0103]

*DRB*

Display Date	5 13 01 4:12 pm
Publication Date	5 21 01
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**Issues Associated With the Intersection of 180-Day Generic Drug Exclusivity and Pediatric Exclusivity; Request for Comments**

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

**ACTION:** Notice; request for comments.

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**SUMMARY:** The Food and Drug Administration (FDA) is establishing the public docket identified in brackets in the heading of this document to receive comments related to the interpretation of provisions of the Federal Food, Drug, and Cosmetic Act (the act) and regulations governing the intersection of 180-day generic drug exclusivity and pediatric exclusivity. To date, there has not been a situation where pediatric exclusivity and 180-day generic exclusivity have actually overlapped. However, FDA has received a large number of inquiries about its interpretation of these provisions and, therefore, is establishing this docket to give the public an opportunity to comment on these issues.

**DATES:** Submit written or electronic comments by [*insert date 30 days after date of publication in the Federal Register*].

**ADDRESSES:** Submit electronic comments to <http://www.fda.gov/ohrms/dockets/default.htm>. Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. 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.

**FOR FURTHER INFORMATION CONTACT:** Rose Cunningham, Center for Drug Evaluation and Research (HFD-6), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5468, FAX 301-594-5493.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Recently FDA has been asked to evaluate the intersection of 180-day generic drug exclusivity and pediatric exclusivity, specifically with respect to whether the exclusivity periods should run concurrently or consecutively. FDA has received written correspondence and telephone inquiries from pharmaceutical firms, organizations, individuals, and members of Congress concerning FDA's interpretation of these provisions. FDA is seeking broader public comment on the intersection of these two statutory provisions.

The 180-day generic drug exclusivity provision was created by the 1984 Drug Price Competition and Patent Term Restoration Act (also known as the Hatch-Waxman Amendments), enacted on September 24, 1984. This provision, contained in section 505(j)(5)(B)(iv) of the act (21 U.S.C. 355(j)(5)(B)(iv)), provides an incentive for generic drug applicants to challenge innovator patent claims and thereby speed the entry of generic competition onto the market. This benefit is available to the first abbreviated new drug application (ANDA) received that is a substantially complete application that contains a "paragraph IV" certification. This type of certification states the ANDA applicant's belief that a patent listed for the innovator drug is invalid or unenforceable or that the ANDA product seeking approval will not infringe a listed patent. Under the terms of the statute, 180-day generic drug exclusivity is triggered by and begins to run from either: (1) A court decision finding the challenged patent invalid, unenforceable, or not infringed; or (2) the date of first commercial marketing of the ANDA drug product, whichever is earlier. During the 180-day generic drug exclusivity period, FDA is prohibited from approving a subsequently filed ANDA containing a paragraph IV certification.

Pediatric exclusivity was created by the passage of the Food and Drug Administration Modernization Act, enacted on November 21, 1997. This provision, contained in section 505A of the act, provides an incentive for innovator companies to perform and submit to the agency pediatric studies that may produce health benefits in the pediatric population. This benefit is available to a new drug application holder for the submission of pediatric studies in response to a written request issued by the agency. Pediatric exclusivity extends for 6 months existing patent and/or exclusivity protection on the innovator drug and begins to run on the date the existing patent and/or exclusivity protection on the innovator drug would otherwise expire. ANDAs referencing the innovator drug may not be approved during the pediatric exclusivity period.

FDA seeks public comment on whether pediatric exclusivity runs concurrently or consecutively with 180-day generic drug exclusivity when a favorable court decision in a paragraph IV patent challenge lawsuit is issued less than 180 days before the beginning of or during the pediatric exclusivity period.

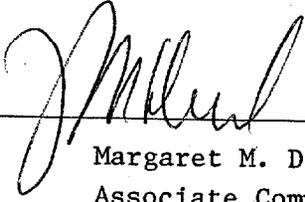
## **II. Request for Comments**

Interested persons may submit to the Dockets Management Branch (address above) written comments by [*insert date 30 days after date of publication in the Federal Register*]. 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. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 5-14-01

cd0182

May 14, 2001.



Margaret M. Dotzel,  
Associate Commissioner for Policy.

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[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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