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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 00N-1266]

**Report to Congress on Pediatric Exclusivity; Request for Comments**

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

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

**SUMMARY:** The Food and Drug Administration (FDA) is requesting comments on the pediatric exclusivity program established by the Food and Drug Administration Modernization Act of 1997 (the Modernization Act). This action is being taken to assist the agency in preparing a report to Congress on pediatric exclusivity as required by the Federal Food, Drug, and Cosmetic Act (the act). FDA is seeking public input on the pediatric exclusivity program.

**DATES:** Submit written comments on the pediatric exclusivity program by *[insert date 30 days after date of publication in the **Federal Register**]*.

**ADDRESSES:** Submit written comments on the pediatric exclusivity program to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Copies of this notice are available on the Internet at <http://www.fda.gov/cder/pediatrics>.

**FOR FURTHER INFORMATION CONTACT:**

Terrie L. Crescenzi, Center for Drug Evaluation and Research (HFD-104), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-7337, FAX 301-827-2520, e-mail: [crescenzit@cder.fda.gov](mailto:crescenzit@cder.fda.gov), or

Elaine C. Esber, Center for Biologics Evaluation and Research (HFM-30), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0641, FAX 301-827-0644, e-mail: [esber@cber.fda.gov](mailto:esber@cber.fda.gov).

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**SUPPLEMENTARY INFORMATION:****I. Background**

FDA is seeking public comment on the pediatric exclusivity program. Section 111 of the Modernization Act (Public Law 105–115), signed into law by President Clinton on November 21, 1997, created section 505A of the act (21 U.S.C. 355a). Section 505A of the act permits certain new drug applications to obtain an additional 6 months of marketing exclusivity if, in accordance with the requirements of the statute, the sponsor submits information relating to the use of the drug in the pediatric population.

Under section 505A(k) of the act, FDA must submit a report to Congress on the pediatric exclusivity program.

**II. Description of the Report**

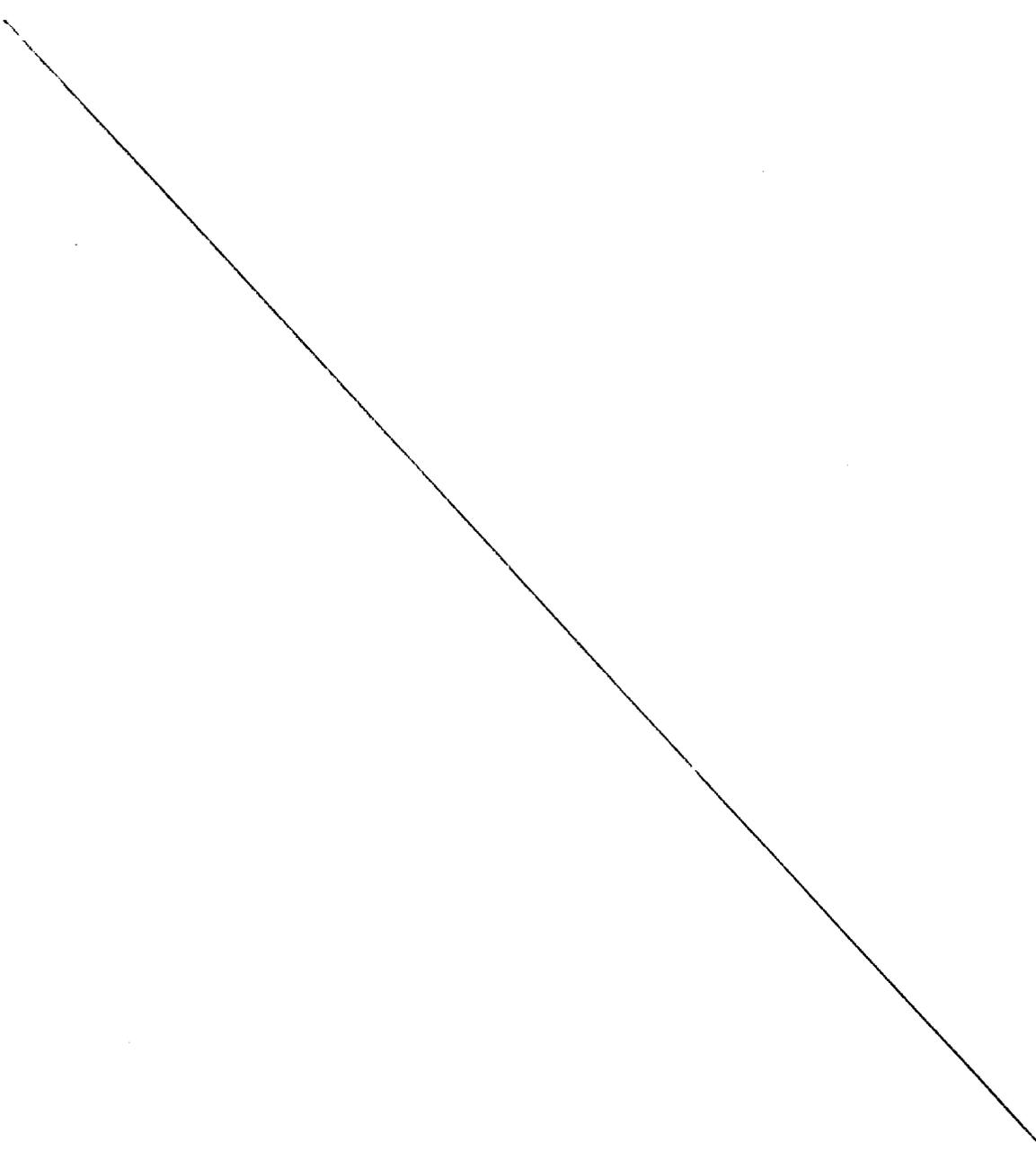
Under section 505A(k) of the act, FDA must conduct a study and report to Congress not later than January 1, 2001, on the experience under the pediatric exclusivity provisions of the act. The study and report must examine all relevant issues, including:

1. The effectiveness of the program in improving information about important pediatric uses for approved drugs;
2. The adequacy of the pediatric exclusivity incentive;
3. The economic impact of the pediatric exclusivity program on taxpayers and consumers and the impact of the lack of lower cost generic drugs on patients, including on lower income patients; and
4. Any suggestions for modification.

**III. Request for Comments**

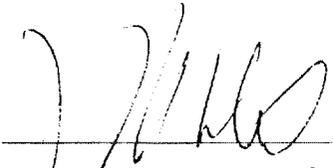
FDA invites all interested parties to address the specific topics that will be included in the report or any other general issue appropriate for this report relevant to the pediatric exclusivity provision of the act. Interested persons may submit to the Dockets Management Branch (address

above) written comments on the pediatric exclusivity program 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: 4/28/00  
April 28, 2000

  
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Margaret M. Dotzel  
Acting Associate Commissioner for Policy

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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