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 June 5, 2000.

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, 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.

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 June 5, 2000. 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: April 28, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–11328 Filed 5–4–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–462A/B]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Clinical Laboratory Improvement Amendments (CLIA) Adverse Action Extract and Supporting Regulations at 42 CFR 483.1840; *Form No.:* HCFA–462A/B (OMB 0938–0655; *Use:* The CLIA Adverse Action Extract will be used by HCFA surveyors (State health department, and other HCFA agents) to report to regional staff and record the adverse actions imposed against a laboratory. The form will also serve to track dates of the imposition of adverse actions, date on which a laboratory corrects deficiencies, and all appeals activity; *Frequency:* On occasion, Biennially; *Affected Public:* State, local, or tribal government; *Number of Respondents:* 52; *Total Annual Responses:* 1573; *Total Annual Hours:* 786.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Julie Brown, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: April 26, 2000.

John P. Burke III,

Reports Clearance Officer, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 00–11215 Filed 5–4–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–1957]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and