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]

BILLING CODE 4160–01–F

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]

BILLING CODE 4120–03–P

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

Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the 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: SSO Report of State Buy In Problems and Supporting Regulations in 42 CFR 407.40;

Form No.: HCFA–1957 (0938–0035);

Use: The HCFA–1957 is issued to assist with communications between the Social Security District Offices, Medicaid State Agencies and HCFA Central Offices in the resolution of beneficiary complaints, regarding entitlement under state buy-ins. It is used when a problem arises which cannot be resolved thru normal data exchange.

Frequency: On occasion;

Affected Public: State, Local or Tribal Government, and Individuals or Households;

Number of Respondents: 2,000;

Total Annual Responses: 2,000;

Total Annual Hours: 716.

To obtain copies of the supporting statement 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 and phone number, 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 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: April 10, 2000.

John P. Burke III,

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

[FR Doc. 00–11216 Filed 5–4–00; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

White House Initiative on Asian Americans and Pacific Islanders President's Advisory Commission; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of May 2000.

Name: President's Advisory Commission on Asian Americans and Pacific Islanders.

Date and Time: May 17, 2000; 9:00 a.m.–5:00 p.m. and May 19, 2000; 9:00 a.m.–5:00 p.m.

Place: Hubert H. Humphrey Building, Room 800, 200 Independence Avenue, SW, Washington, D.C. 20201.

The meetings are open to the public.

The President's Advisory Commission will have its inaugural meeting on May 17, from 9:00 a.m.–5:00 p.m. and subsequent meeting on May 19, from 9:00 a.m.–5:00 p.m. The purpose of the Commission is to advise the President on the issues facing Asian Americans and Pacific Islanders (AAPIs). The President's Advisory Commission on AAPIs will be seated through June 7, 2001. Agenda items will include, but will not be limited to: orientation; rolls and responsibilities of Commissioners; updates on the activities of the White House Initiative on AAPIs; and discussion of future Commission activities. Agenda items are subject to change as priorities dictate.

Requests to address the Commission should be made in writing and should include the name, address, telephone number and business or professional affiliation of the interested party. Individuals or groups addressing similar issues are encouraged to combine comments and present through a single representative. The allocation of time for remarks may be adjusted to accommodate the level of expressed interest. Written requests should be faxed to (301) 443–0259. Anyone who has interest in attending any portion of the meeting or who requires additional information about the Commission should contact: Mr. Tyson Nakashima, Office of the White House Initiative on AAPIs, Parklawn Building, Room 10–42, 5600 Fishers Lane, Rockville, MD 20857, Telephone (301) 443–2492. Anyone who requires special assistance, such as sign language interpretation or other reasonable accommodations, should contact Mr. Nakashima no later than May 10, 2000.

Dated: May 3, 2000.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 00–11449 Filed 5–4–00; 8:45 am]

BILLING CODE 4160–15–p

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of June 2000.

Name: Advisory Commission on Childhood Vaccines (ACCV).

Date and Time: June 7, 2000; 9 a.m.–5 p.m.

Place: Parklawn Building, Conference Rooms G & H, 5600 Fishers Lane, Rockville, Maryland 20857.

The meeting is open to the public.

The full Commission will meet on Wednesday, June 7, from 9 a.m. to 5 p.m. Agenda items will include, but not be limited to: a presentation on Aluminum in Vaccines, a presentation on recent General Accounting Office Reports on the Vaccine Injury Compensation Program, a report on Vaccination and Autism, updates from the Department of Justice and the National Vaccine Program Office, and routine program reports.

Public comment will be permitted before lunch and at the end of the Commission meeting on June 7, 2000. Oral presentations will be limited to 5 minutes per public speaker. Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to: Ms. Shelia Tibbs, Principal Staff Liaison, Division of Vaccine Injury Compensation, Bureau of Health Professions, Health Resources and Services Administration, Room 8A–46, 5600 Fishers Lane, Rockville, MD 20857, Telephone (301) 443–1896. Requests should contain the name, address, telephone number, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest.