DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Head Start Program Information Report (PIR).

OMB No.: 0980–0017.

Description: The Head Start Act requires that the Program Information Report (PIR) information is collected from Head Start grantees and delegate agencies. Data elements are primarily in the areas of management, class activity, health profile and home environment. Principle user of the date include local program management, ACF regional management, ACYF central office management, management of services to children with disabilities, and dissemination to other interested parties.

Respondents: Head Start Grantees and Delegate Agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
PIR	2,078	4	3.35	6,691

Estimated Total Annual Burden Hours: 6,691.

Additional Information: Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, N.W., Washington, D.C. 20503, Attn: Ms. Wendy Taylor.

Dated: November 3, 1997.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 97–29468 Filed 11–6–97; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Collection of Child Welfare data under the Voluntary Cooperative Information System (VCIS).

OMB No.: 0970–0129.

Description: The objective of VCIS is to provide current data on the characteristics of children in, and the flow of children through, State foster care and adoption systems. These data also are utilized to identify State and national trends for the types of children in care, the settings in which children receive care, and the outcomes of substitute care episodes.

The VCIS data are used to respond to requests for current data on children in foster care as well as those awaiting adoption and recently adopted. These data are also used for preparing Congressional testimony and reports, proposing policy and legislative changes, determining foster care and adoption trends and projections, and making budget forecasts. In addition, the VCIS data are made available to researchers and evaluators as well as the media. These data also appeared in the 1996 Green Book, which contains background material and data on programs within the jurisdiction of the Congressional Committee on Ways and Means.

Respondents: State Governments, Guam, Virgin Islands, Puerto Rico and District of Columbia.

Annual burden estimates

Instrument:	
VCIS Survey:	
Number of Respondents ..	54
Number of Responses per Respondent	1
Average Burden Hours per Response	3
Total Burden Hours	162

Estimated Total Annual Burden Hours: 162.

Additional Information: Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, Attn: Ms. Wendy Taylor.

Dated: November 3, 1997.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 97–29469 Filed 11–6–97; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 93N–0451]

James Michael Anthony; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the act) permanently debarring James Michael Anthony, M.D., 130 North McLean, Memphis, TN 38104, from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Dr. Anthony was convicted of a felony under Federal law for

conduct relating to the regulation of a drug product under the act. Dr. Anthony has failed to request a hearing and, therefore, has waived his opportunity for a hearing concerning this action.

EFFECTIVE DATE: November 7, 1997.

ADDRESSES: Application for termination of debarment to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Leanne Cusumano, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

On July 26, 1993, the U.S. District Court for the Western District of Tennessee accepted Dr. Anthony's plea of guilty and entered judgment against him for, among other counts, one count of trading prescription drug samples, a Federal felony offense under section 503(c)(1) of the act (21 U.S.C. 353(c)(1)). This felony conviction was based on the unlawful trade of a drug sample of Ansaid Tablets, which was not intended to be sold but rather was intended to promote the sale of the drug, in exchange for the drug Rocephin.

As a result of this conviction, FDA served Dr. Anthony by certified mail on October 12, 1994, a notice proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application, and offered him an opportunity for a hearing on the proposal. The proposal was based on a finding, under section 306(a)(2)(B) of the act (21 U.S.C. 335a(a)(2)(B)), that Dr. Anthony was convicted of a felony under Federal law for conduct relating to the regulation of a drug product. Dr. Anthony was given 30 days to file objections and request a hearing. Dr. Anthony did not file objections or request a hearing. His failure to request a hearing constitutes a waiver of his opportunity for a hearing and a waiver of any contentions concerning his debarment.

II. Findings and Order

Therefore, the Director of the Center for Drug Evaluation and Research, under section 306(a) of the act, and under authority delegated to her (21 CFR 5.99(b)), finds that Dr. James Michael Anthony has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product.

As a result of the foregoing finding, Dr. James Michael Anthony is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 507, 512, or 802 of the act (21 U.S.C. 355, 357, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective November 7, 1997 (sections 306(c)(1)(B) and (c)(2)(A)(ii) and 201(dd) (21 U.S.C. 321(dd))). Any person with an approved or pending drug product application who knowingly uses the services of Dr. Anthony, in any capacity, during his period of debarment, will be subject to civil money penalties (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6))). If Dr. Anthony, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties (section 307(a)(7) of the act). In addition, FDA will not accept or review any abbreviated new drug applications or abbreviated antibiotic drug applications submitted by or with the assistance of Dr. Anthony during his period of debarment.

Any application by Dr. Anthony for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 93N–0451 and sent to the Dockets Management Branch (address above). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 29, 1997,

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 97–29399 Filed 11–6–97; 8:45 am]

BILLING CODE 4160–01–F

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 are scheduled to meet during the month of December 1997:

Name: HRSA Aids Advisory Committee.

Time: December 2–3, 1997 9:00 a.m.

Place: Loews L'Enfant Hotel, 80 L'Enfant Plaza, S.W., Washington, D.C. 20024.

The meeting is open to the public.

Agenda: The topics to be discussed include the reorganization of the Ryan White CARE Act programs; Clinical Guidelines; and Access to Combination Therapies and Adherence Issues.

Anyone requiring information regarding the subject Committee should contact Joan Holloway, HIV/AIDS Bureau, Health Resources and Services Administration, Room 7–13, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–9530.

Agenda Items are subject to change as priorities dictate.

Dated: November 3, 1997.

Jane M. Harrison,

Advisory Committee Management Office, HRSA.

[FR Doc. 97–29482 Filed 11–6–97; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Institute of Child Health and Human Development Special Emphasis Panel (SEP) meeting:

Name of Sep: Initiation of Human Labor: Prevention of Prematurity.

Date: November 6–7, 1997.

Time: November 6—7:30 p.m.–10 p.m.; November 7—8:30 a.m.—adjournment.

Place: University of South West Medical Center/Dallas, 5323 Harry Hines Boulevard, Dallas, Texas 75235.

Contact Person: Gopal M. Bhatnagar, Ph.D., Scientific Review Administrator, NICHD, 6100 Executive Boulevard, Room 5E01, Rockville, MD 20852, Telephone: 301–496–1485.

Purpose/Agenda: To evaluate and review a research grant application.

This meeting will be closed in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C. The discussion of this application could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the application, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.