Federal Food, Drug, and Cosmetic Act.'' On November 21, 1997, the President signed the Modernization Act (Pub. L. 105–115). Section 127 of the Modernization Act, which adds section 503A to the act (21 U.S.C. 353a), clarifies the status of pharmacy compounding under Federal law. Under section 503A of the act, drug products that are compounded by a pharmacist or physician on a customized basis for an individual patient may be entitled to exemptions from three key provisions of the act: (1) The adulteration provision of section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning the good manufacturing practice requirements), (2) the misbranding provision of section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use), and (3) the new drug provision of section 505 (21 U.S.C. 355) (concerning the approval of drugs under new drug or abbreviated new drug applications).

To qualify for these statutory exemptions, a compounded drug product must satisfy several requirements, some of which are to be the subject of FDA's rulemaking or other actions. FDA is currently working on several rules and other documents necessary to implement section 503A of the act. However, section 503A of the act takes effect on November 21, 1998, and FDA will not have completed its implementation efforts by this date. This guidance document describes FDA's policy on enforcement of section 503A of the act during the transition to full implementation of that provision.

This guidance document is being issued as a Level 1 guidance consistent with FDA's ''Good Guidance Practices'' (62 FR 8961, February 27, 1997). It is being implemented immediately without prior public comment because the guidance document is needed to explain to industry the agency's current policy on enforcement of section 503A of the act, which will take effect November 21, 1998. However, the agency wishes to solicit comment from the public and is providing a 90-day comment period and establishing a docket for the receipt of comments.

This guidance document represents the agency's current thinking on enforcement of section 503A of the act during the transition to full implementation. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

II. Comments

Interested persons may, on or before February 22, 1999, submit to the Dockets Management Branch (address above) written comments on the guidance document. 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. The guidance document and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document using the World Wide Web (WWW). For WWW access, connect to CDER at ''http://www.fda.gov/cder/guidance.htm''.

Dated: November 17, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–31221 Filed 11–20–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–P–15A & HCFA–37]

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.

(1) *Type of Information Collection Request:* New Collection.

Title of Information Collection: Medicare Information Needs: Supplement to the Medicare Current Beneficiary Survey (MCBS).

Form No.: HCFA–P–15A (OMB# 0938–NEW).

Use: This supplement to the MCBS builds upon the previously fielded Round 18 Supplement, which provided useful information to HCFA's Center for Beneficiary Services on beneficiary information needs and preferences for how to receive information. Results from this data collection will be used by HCFA to guide continued development of communication and education programs for Medicare beneficiaries.

Affected Public: Individuals or Households.

Number of Respondents: 12,000.

Total Annual Responses: 12,000.

Total Annual Hours: 3,000.

(2) *Type of Information Collection Request:* Revision of a currently approved collection.

Title of Information Collection: Medicaid Program Budget Reports and Supporting Regulations in 42 CFR Section 430.30.

Form No.: HCFA–37 (OMB# 0938–0101).

Use: The Medicaid Program Budget report is prepared by the State Medicaid Agencies and is used by HCFA for (1) developing National Medicaid Budget estimates, (2) quantifying Budget Assumptions, (3) issuing quarterly Medicaid Grant Awards, and (4) collecting projected State receipts of donations and taxes.

Frequency: Quarterly.

Affected Public: State, Local or Tribal Government.

Number of Respondents: 57.

Total Annual Responses: 224.

Total Annual Hours: 7,840.

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: Dawn Willinghan, Room N2–14–26 7500 Security Boulevard Baltimore, Maryland 21244–1850

Dated: November 13, 1998.

John P. Burke III,

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

[FR Doc. 98–31236 Filed 11–20–98; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Council on Graduate Medical Education 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 December 1998:

Name: Council on Graduate Medical Education.

Date and Time: December 16, 1998, 8:30 a.m.–5 p.m.; December 17, 1998, 8:30 a.m.–1 p.m.

Place: Omni Shoreham Hotel, 2500 Calvert Street, NW, Washington, DC.

This meeting is open to the Public.

Agenda: The agenda will include: Welcome and opening comments from the Administrator, Health Resources and Services Administration, the Associate Administrator for Health Professions and the Acting Executive Secretary of COGME; a panel on GME Financing Issues; a panel on GME Program Issues; and a panel on Medical Education in Integrated Settings. The Council will hear an update on Progress in Minority Entry into Medicine. It will discuss the COGME 15th Report outline, and its future direction.

Anyone requiring information regarding the subject should contact F. Lawrence Clare, M.D., M.P.H., Deputy Executive Secretary, telephone (301) 443–6326, Council on Graduate Medical Education, Division of Medicine, Bureau of Health Professions, Room 9A–27, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

Agenda items are subject to change as priorities dictate.

Dated: November 17, 1998.

Jane M. Harrison,

Director, Division of Policy and Review Coordination.

[FR Doc. 98–31222 Filed 11–20–98; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Research and Demonstration Projects for Indian Health

AGENCY: Indian Health Service, HHS.

ACTION: Notice of Single Source Cooperative Agreement with the National Council of Urban Indian Health.

SUMMARY: The Indian Health Service (HHS) announces the award of a cooperative agreement to the National Council of Urban Indian Health (NCUIH) for a demonstration project for urban Indian health care advocacy, consultation, health data dissemination, training, and technical assistance. The project is for a three-year project period effective September 30, 1998, to August 31, 2001. Funding for the project is $412,170.

The award is issued under the authority of the Public Health Service Act, section 301, and is listed under Catalog of Federal Domestic Assistance number 93.933.

The specific objectives of the project are:

1. To provide various forms of technical assistance to member organizations, with subject matter varying according to member need and NUCIH initiatives.

2. To advocate on behalf of Title V programs and their consumers.

3. To disseminate information in a timely and accurate manner by means of a quarterly newsletter and establishment of a web page.

4. To coordinate two meetings for the general membership to conduct business and develop policy strategies.

Justification for Single Source

This project has been awarded on a non-competitive single source basis. NCUIH is the only nationwide Indian organization that is specifically established to address the health needs of American Indians living in urban areas with membership consisting of Title V urban Indian organizations. Furthermore, it is the only nationwide organization of urban Indians supporting the growth of the urban Indian health care delivery system.

Use of Cooperative Agreement

A cooperative agreement has been awarded because of anticipated substantial programmatic involvement by IHS staff in the project. Substantial programmatic involvement is as follows:

1. IHS staff will participate in at least one Board meeting annually. Purposes will be to present the IHS prospectus on current health care and legislative issues affecting the urban Indian people.

2. IHS staff will approve articles to be included in newsletters.

3. IHS staff may, at the request of NCUIH, participate on study groups and may recommend topics for consideration.

4. IHS will be involved in the selection and approval process for hiring key personnel. Key personnel include the Chief Executive Officer, Administrative Assistant, and consultants. NCUIH must submit the Chief Executive Officer selection criteria to IHS for approval.

5. IHS will be involved in the agenda for the Roundtable meeting in November 1998 and the annual Leadership meeting in March 1999.

CONTACTS: For program information, contact Mr. James F. Cussen, Director, Urban Programs, Office of the Director, Indian Health Service, Room 6–12, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20852 (301) 443–4680. For grants management information, contact Mrs. M. Kay Carpentier, Grants Management Officer, Division of Acquisition and Grants Management, Suite 100, Twinbrook Metro Plaza, 12300 Twinbrook Parkway, Rockville, Maryland 20852 (301) 443–5204.

Dated: November 13, 1998.

Michael H. Trujillo,

Assistant Surgeon General, Director.

[FR Doc. 98–31223 Filed 11–20–98; 8:45 am]

BILLING CODE 4160–16–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Meeting of the Advisory Committee to the Director, NIH

Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the Advisory Committee to the Director, NIH, December 3, 1998, Conference Room 10, Building 31, National Institutes of Health, Bethesda, Maryland 20892.

The entire meeting will be open to the public from 8:30 a.m. to adjournment. The topics proposed for discussion include (1) Review of the Human Genome Project; (2) Issues Regarding the Intramural Program; (3) Priority Setting; and (4) Issues Related to Clinical Trials and the Clinical Trials Database. Attendance by the public will be limited to space available.

Ms. Janice Ramsden, Special Assistant to the Deputy Director, National Institutes of Health, 1 Center Drive MSC 0159, Bethesda, Maryland 20892–0159, telephone (301) 496–0959, fax (301) 496–7451, will furnish the meeting agenda, roster of committee members, and available substantive program information upon request. Any individual who requires special assistance, such as sign language