about any matter under FDA's jurisdiction.

In addition, there are specific provisions and procedures that apply to or are used by the Centers. For example, FDA's new drug regulations provide procedures for dispute resolution regarding new drug applications. These procedures include informal meetings with the division reviewing the application, meetings with an ombudsman, and referrals to advisory committees (see § 314.103 (21 CFR 314.103)). The new drug regulations also provide the sponsor an opportunity for a hearing on the question of whether there are grounds for denying approval of the application (see § 314.110 (21 CFR 314.110)). CBER's review letters (''approvable'' and ''not approvable'') state the sponsor's options for appeal. Specifically, CBER's ''not approvable'' letter informs the sponsor that it may request a meeting with CBER to discuss the steps needed for approval or may request an opportunity for a hearing.

Finally, persons with concerns about the application of guidance documents may contact the FDA Office of the Chief Mediator and Ombudsman (the Ombudsman's Office). The Ombudsman's Office, which reports directly to the Commissioner, works on resolving issues and conflicts that arise in any FDA component. The Ombudsman's staff is available to discuss options, explain FDA's practices and procedures, and suggest approaches for resolution. When appropriate, the staff of the Ombudsman's Office may contact the FDA staff involved in the issue and mediate a dispute.

As the above discussion indicates, FDA already has a significant number of appeals mechanisms—all of which can be used by persons dissatisfied with how guidance is being applied. The agency recently established a working group to address the consistency and adequacy of dispute resolution processes across the agency and the effectiveness of education regarding the availability of such processes to industry. FDA is soliciting comment on whether the public is sufficiently aware of the appeals mechanisms that are in place and whether the public believes that the mechanisms are sufficient for appealing decisions relating to guidance documents. If the answer is that the mechanisms in place are not sufficient, FDA would like to hear why they are not and would like to receive suggestions on alternate methods or ways to improve our current procedures.

II. Summary of Issues for Comment

Sections I. A. through I. E. of this document set forth a number of issues about which the agency would like to receive public comment. A summary of those issues is set forth below:

(1) FDA is soliciting comment on the value of a standardized nomenclature for guidance documents. If a standardized nomenclature is desirable, FDA is soliciting comment on what that nomenclature should be and the best approach to take regarding the nomenclature of existing guidance.

(2) FDA is soliciting comment on how best to communicate to its own staff and to the public the principle that guidance is not binding.

(3) FDA is soliciting comment on the proposed three-tiered approach to public input (including comment on how to classify documents as tier 1, 2, or 3) and/or suggestions for alternatives to the three-tiered approach. FDA also wants to hear whether public access to comments should be included as a part of good guidance practices. Finally, FDA is soliciting comment regarding how FDA should notify the public of new guidance and how the public can notify FDA of the need for guidance.

(4) FDA is soliciting comment on the adequacy of its current guidance document access programs and suggestions for improving access to guidance documents.

(5) FDA is soliciting comment on whether the public is sufficiently aware of current appeals mechanisms and whether the mechanisms are sufficient for appealing decisions relating to guidance documents. If the current processes are not sufficient, FDA would like to hear why they are not and would like to receive suggestions on alternate methods or ways to improve the current procedures.

Interested persons may, on or before June 5, 1996, submit to the Dockets Management Branch (address above) written comments regarding this 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 29, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–5344 Filed 3–6–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95N–0200]

Regulatory Approach To Products Comprised of Living Autologous Cells Manipulated Ex Vivo and Intended for Structural Repair or Reconstruction; FDA Commissioner's Roundtable; Notice of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a FDA Commissioner's roundtable public meeting on the regulatory approach to products comprised of living autologous cells manipulated ex vivo and intended for structural repair or reconstruction. The purpose of this meeting is to discuss FDA's current thinking on the regulatory approach of these products with respect to clinical and manufacturing issues, and to get input on the agency's tentative approach. The comments received to the Dockets Management Branch in response to an earlier hearing held on November 16 and 17, 1995, will also be discussed.

DATES: The Commissioner's roundtable public meeting will be held on Friday, March l5, l996, from 8 a.m. to 5 p.m.

ADDRESSES: The Commissioner's roundtable public meeting will be held at the Parklawn Bldg., 5600 Fishers Lane, third floor, conference rooms C and D, Rockville, MD.

FOR FURTHER INFORMATION CONTACT: Emma J. Knight, Office of Blood Research and Review (HFM–305), Center for Biologics Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0969. Those persons interested in attending this meeting should FAX their registration to Emma J. Knight, 30l–827–2844, or Jeanne White, 30l–827–0926, including name(s), affiliation, address, telephone and FAX numbers by March l3, 1996. There is no registration fee for this public meeting, but advance registration is required. Space is limited and all interested parties are encourage to register early.

SUPPLEMENTARY INFORMATION: The purpose of this public meeting is to interact with interested persons on the good manufacturing practice and clinical issues related to products comprised of living autologous cells manipulated ex vivo and intended for surgical repair or reconstruction, and to discuss FDA's approach to these issues. FDA will take this public discussion into consideration in reaching a final decision on the approach the agency will take.

Dated: February 29, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–5584 Filed 3–5–96; 3:44 pm]

BILLING CODE 4160–01–F

Health Care Financing Administration

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 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: Revision of a currently approved collection; *Title of Information Collection:* Hospital and Hospital Healthcare Complex Cost Report; *Form No.:* HCFA–2552–96; *Use:* This form is required by statute and regulation for participation in the Medicare program. The information is used to determine final payment for Medicare. Hospitals and related complexes are the main users. *Frequency:* Annually; *Affected Public:* Business or other for-profit, Not-for profit institutions, and State, local or tribal government; *Number of Respondents:* 7,000; *Total Annual Responses:* 7,000; *Total Annual Hours Requested:* 4,599,000. To request copies of the proposed paperwork collections referenced above, call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections should be sent within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Financial and Human Resources, Management Planning and Analysis Staff, Attention: Louis Blank, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: February 29, 1996.

Kathleen B. Larson,

Director, Management Planning and Analysis Staff, Office of Financial and Human Resources.

[FR Doc. 96–5347 Filed 3–6–96; 8:45 am]

BILLING CODE 4120–03–P

Health Resources and Services Administration

Special Projects of National Significance, Evaluation Technical Assistance Center; Correction

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Correction.

SUMMARY: The Notice of Availability of Funds, Special Projects of National Significance, Evaluation Technical Assistance Center, which was published on February 28, 1996, at 61 FR 7527, is corrected to include the following:

Eligible Applicants

The statute, Section 2618(a)(1), specifies that grants may be awarded to public and non-profit entities to develop models of care for the treatment of people with HIV infection and disease. Eligible entities may include, but are not limited to, State, local, or tribal public health, mental health, or substance abuse departments; public or non-profit hospitals and medical facilities; community-based service organizations (e.g., AIDS service organizations, primary health care clinics, family planning centers, AIDS discrimination and advocacy organizations, hemophilia centers, community health or mental health centers, substance abuse treatment centers, urban and tribal Indian health centers or facilities, migrant health centers, etc.); institutions of higher education; and national service provider and/or policy development associations/organizations.

Dated: March 1, 1996.

John D. Mahoney,

Acting Administrator.

[FR Doc. 96–5293 Filed 3–6–96; 8:45 am]

BILLING CODE 4160–15–P

Special Projects of National Significance; Integrated Service Delivery Models

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Correction.

SUMMARY: The Notice of Availability of Funds, Special Projects of National Significance, Integrated Service Delivery Models, which was published on February 28, 1996, at 61 FR 7525, is corrected to include the following:

Eligible Applicants

The statute, Section 2618(a)(1), specifies that grants may be awarded to public and non-profit entities to develop models of care for the treatment of people with HIV infection and disease. Eligible entities may include, but are not limited to, State, local, or tribal public health, mental health, housing, or substance abuse departments; public or non-profit hospitals and medical facilities; community-based service organizations (e.g., AIDS service organizations, primary health care clinics, family planning centers, AIDS discrimination and advocacy organizations, homeless assistance providers, hemophilia centers, community health or mental health centers, substance abuse treatment centers, urban and tribal Indian health centers or facilities, migrant health centers, etc.); institutions of higher education; and national service provider and/or policy development associations/organizations.

Dated: March 1, 1996.

John D. Mahoney,

Acting Administrator.

[FR Doc. 96–5294 Filed 3–6–96; 8:45 am]

BILLING CODE 4160–15–P

Special Projects of National Significance; Health Care Services Demonstration Models for Youth Infected With HIV

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of availability of funds.

SUMMARY: The Health Resources and Services Administration (HRSA) announces the availability of $1,900,000 in fiscal year (FY) 1996 funds to be awarded under the Special Projects of National Significance (SPNS) program. HRSA expects to award three to five grants for approximately $380,000 - $633,000 each for a three year project period for Health Care Services Demonstration Models for Youth Infected with HIV. The SPNS program is authorized by Section 2618 (a) of the Public Health Service Act. This announcement solicits innovative services demonstration models of providing health and related support services for youth with HIV infection.