supersedes the "Nuclear Pharmacy Guideline; Criteria for Determining When to Register as a Drug Establishment" issued by FDA in May 1984.

A. Physiological Research

Facilities using PET radiopharmaceuticals for purely physiological research, where the results of such research are not used to guide patient management or treatment decisions, should establish a PET Regulatory Committee (PRC) in accordance with §1A361.1 Radioactive drugs for certain research uses (21 CFR 361.1). The PRC will monitor all physiological research of the PET facility. Facilities using PET radiopharmaceuticals for purely physiological research are not required to submit an investigational new drug application (IND) or NDA as long as this research is intended to obtain basic information regarding metabolism or physiology and is not intended to guide or be part of therapeutic, diagnostic, or clinical management plans.

FDA will approve and monitor the PRC, which should consist of at least five individuals. In accordance with §1A361.1(c), each PRC should include: (1) A physician recognized as a specialist in nuclear medicine; (2) a person qualified by training and experience to manufacture PET radiopharmaceuticals; and (3) a person with special competence in radiation safety and radiation dosimetry. The remaining PRC members should include individuals qualified in various disciplines pertaining to the field of nuclear medicine, and should be sufficiently diverse to permit expert review of the technical and scientific aspects of proposals submitted to the committee. In addition to the requirements in §1A361.1(c) and with the exception of the member qualified by training and experience to manufacture PET radiopharmaceuticals, PRC membership should include a representative of a consumer group, and the members should not have scientific, clinical, financial, or administrative conflicts of interest.

The PRC should have three main responsibilities: (1) To approve research protocols; (2) to prepare annual reports; and (3) to determine when purely physiological research has ended.

In approving protocols, the PRC should: (1) Determine if the investigator meets the qualifications specified in the protocol; (2) review the research protocol design; (3) review and monitor the selection of research subjects; (4) ensure that the research subjects have signed informed consent documents; (5)

review and monitor the quality of the PET radiopharmaceuticals administered; (6) evaluate all reports of adverse events; and (7) confirm concurrence of Institutional Review Board approval.

The annual report should follow the format and contents prescribed in \$1A361.1(c)(3), summarizing the conditions of use, doses, route of administration, protocols, adverse events reported in the safety information, and the chemistry, manufacturing, and control data. The PRC should submit the completed annual report to FDA.

The PRC is also responsible for determining when purely physiological research becomes investigational clinical use. This determination should be based on whether the data obtained will be used in the diagnostic, therapeutic, or clinical management of patients. Once trials are proposed for investigational clinical use, the facility must submit an IND before starting to conduct the trials.

B. Investigational Use

Manufacturers of PET radiopharmaceuticals intended to be used in investigational clinical trials must submit an IND to FDA in accordance with the regulations in part 312. Institutions or investigators working together with the same PET radiopharmaceutical may submit one IND for that drug product, covering studies conducted at more than one site or institution.

C. NDA Approval

Submission of an NDA, in accordance with FDA regulations in part 314 (21 CFR part 314), is required for PET radiopharmaceuticals used in clinical practice. Institutions or investigators working together with the same PET radiopharmaceutical may submit one NDA for that drug product. All sites that produce the same drug product would be covered by the submitted NDA. Once an NDA is approved, other PET facilities with a radiopharmaceutical that is an equivalent finished product, but which did not participate in the NDA or did not submit manufacturing data, could submit an abbreviated new drug application (ANDA) demonstrating that their drug is bioequivalent to the innovator drug, in accordance with FDA regulations in part 314. Alternatively, the NDA holder could submit a supplement to add these other facilities as new manufacturing sites.

PET radiopharmaceuticals are also subject to the adulteration and misbranding provisions of the act. Facilities where PET radiopharmaceuticals are manufactured are subject to inspection by FDA for compliance with CGMP requirements and other drug-related requirements.

Dated: February 17, 1995.
William B. Schultz,
Deputy Commissioner for Policy.
[FR Doc. 95–4691 Filed 2–24–95; 8:45 am]
BILLING CODE 4160–01–F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Public and Indian Housing

[Docket No. N-55-3710; FR-3636--03]

Announcement of Funding Awards Public Housing Drug Elimination Technical Assistance Program, FY 1994

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Announcement of funding awards.

SUMMARY: In accordance with section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989, this announcement notifies the public of funding decisions made by the Department in a competition for funding under the Notice of Funding Availability (NOFA) for Public Housing Drug Elimination-Technical Assistance Program. This announcement contains the names and addresses of the award winners and the amount of the awards.

FOR FURTHER INFORMATION CONTACT:

Elizabeth Cocke, Drug Free Neighborhoods Division, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 4116, Washington, DC 20410, telephone (202) 708–1197. A telecommunications device for hearing or speech impaired persons (TDD) is available at (202) 708–0850. (These are not toll-free numbers.)

SUPPLEMENTARY INFORMATION: The Public Housing Drug Elimination-Technical Assistance Program is authorized by the Departments of Veterans Affairs and Housing and Urban Development, and Independent Agencies Appropriations Act, 1994 (approved October 28, 1993, Pub. L. 103–124).

The NOFA published in the Federal Register on March 10, 1994 (59 FR 11418) announced the FY 1994 availability of \$1,255,175 to fund qualified applicants selected under the FY 1993 NOFA and invited additional applicants for FY 1994. The purpose of