divisions in CDER, it appeared that the procedures specified in the regulations were, in general, being followed, and that clinical holds were scientifically supportable. Second, FDA established a committee in CDER to review selected clinical holds for scientific and procedural quality. The committee held pilot meetings in 1991 and met quarterly through 1992. The committee currently meets semiannually as a regular program. The committee last met in June 1995.

CBER has now begun a similar process to evaluate the consistency and fairness of CBER's practices in imposing clinical holds. CBER is beginning by instituting a review committee to review recent clinical holds. CBER also plans to conduct further quality assurance oversight of the IND process. CBER held its first clinical hold review committee meeting on May 17, 1995, and intends to make the clinical hold review process a regular, ongoing program. The review procedure of the committee is designed to afford an opportunity for a sponsor who does not wish to seek formal reconsideration of a pending clinical hold to have that clinical hold considered ''anonymously.'' The committee consists of senior managers of CBER, a senior official from CDER, and FDA's Chief Mediator and Ombudsman.

Clinical holds to be reviewed will be chosen randomly. In addition, the committee will review clinical holds proposed for review by biological product sponsors. In general, a biological product sponsor should consider requesting review when it disagrees with the agency's scientific or procedural basis for the decision.

Requests for committee review of a clinical hold should be submitted to FDA's Chief Mediator and Ombudsman, who is responsible for selecting clinical holds for review. The committee and CBER staff, with the exception of the FDA Chief Mediator and Ombudsman, are never advised, either in the review process or thereafter, which of the clinical holds were randomly chosen and which were submitted by sponsors. The committee will evaluate the selected clinical holds for scientific content and consistency with agency regulations and CBER policy.

The meetings of the review committee are closed to the public because committee discussions deal with confidential commercial information. Summaries of the committee deliberations, excluding confidential commercial information, will be available from the FDA Chief Mediator and Ombudsman. If the status of a clinical hold changes following the committee's review, the appropriate division will notify the sponsor.

FDA invites biological product companies to submit to the FDA Chief Mediator and Ombudsman the name and IND number of any investigational new biological product trial that was placed on clinical hold during the past 12 months that they want the committee to review at its October 1995 meeting. Submissions should be made by October 10, 1995, to Amanda B. Pederson, FDA Chief Mediator and Ombudsman (address above).

Dated: September 20, 1995.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 95–24072 Filed 9–27–95; 8:45 am]

BILLING CODE 4160–01–F

Grassroots Regulatory Partnership; Northeast Region Importing Community; Notice of a Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of a public meeting.

SUMMARY: The Food and Drug Administration (FDA) (Office of Regulatory Affairs, Office of the Northeast Region, Office of External Affairs) is announcing a free public meeting to discuss ways FDA could regulate imported commodities more efficiently, improve levels of communication with industries and individuals associated with the importation of FDA-regulated commodities, and provide improved levels of consumer protection in connection with imported commodities. This meeting is intended to identify and evaluate opportunities for implementing the President's initiative for a partnership approach between the agency and the people affected by the work of this agency.

DATES: The public meeting will be held on September 28, 1995, from 9 a.m. to l p.m.

ADDRESSES: The public meeting will be held at the Fort Hamilton Community Club, Jackson and Washington Rooms, Fort Hamilton (Bay Ridge), Brooklyn, NY 11252.

FOR FURTHER INFORMATION CONTACT:

Barbara A. Miller or Herman B. Janiger, Northeast Region, Food and Drug Administration, 850 Third Ave., Brooklyn, NY 11232, 718–965–5300, ext. 5754 (B. Miller) or ext. 5043 (H. Janiger).

To register for the meeting contact Barbara A. Miller by FAX 718–965–5117, or telephone 718–965–5300, ext. 5754 with the following information: Your name(s), affiliation, address, telephone and FAX numbers, and any specific questions you want addressed at the public meeting.

SUPPLEMENTARY INFORMATION: The meeting is free of charge, however, registration is required and due to space limitation, early registration is recommended. The meeting is intended to assist importers, brokers, and others associated with a wide variety of products being shipped through the east coast (the FDA Northeast and Mid-Atlantic Regions).

Dated: September 25, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–24155 Filed 9–25–95; 3:37 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Housing—Federal Housing Commissioner

[Docket No. FR–3854–N–02]

Notice of Accepted Bid for the Section 221(g)(4) Multifamily Project Mortgage Auction

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice of Accepted Auction Bid.

SUMMARY: Section 221(g)(4)(C) of the National Housing Act requires that the Secretary of HUD cause Federal Register publication of the accepted bid in a multifamily project mortgage auction. Accordingly, this notice announces the name of the auction winner and the amount of the accepted bid for the auction conducted on June 28, 1995.

FOR FURTHER INFORMATION CONTACT: Audrey Hinton, Associate Director, Office of Multifamily Asset Management and Disposition, Dept. HUD, Room 6160, 451 Seventh Street, SE., Washington, DC, 20410, telephone (202) 708–3730. Hearing- or speech-impaired individuals may call HUD's TDD number (202) 708–4594. (These telephone numbers are not toll-free.)

SUPPLEMENTARY INFORMATION: The National Housing Act (12 U.S.C. 1701–1749aaa–5) (the Act) authorizes and governs the Department's mortgage insurance programs. On June 28, 1995, the Department, pursuant to the provisions of Section 221(g)(C)(i) of the Act, conducted the fifth auction of