reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than October 12, 1995.

A. Federal Reserve Bank of Philadelphia (Michael E. Collins, Senior Vice President) 100 North 6th Street, Philadelphia, Pennsylvania 19105:

1. Peoples Savings Financial Corporation, Ridgway, Pennsylvania; to engage *de novo* in lending activities, pursuant to § 225.25(b)(1) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, September 22, 1995.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 95–24075 Filed 9–27–95; 8:45 am]

BILLING CODE 6210–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Investigational New Biological Product Trials; Procedure to Monitor Clinical Hold Process; Meeting of Review Committee and Request for Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a meeting of the clinical hold review committee, which reviews the clinical holds that the Center for Biologics Evaluation and Research (CBER) has placed on certain investigational new biological product trials. CBER held its first clinical hold review committee meeting on May 17, 1995. FDA is inviting any interested biological company to use this confidential mechanism to submit to the committee for its review the name and number of any investigational new biological products trial placed on clinical hold during the past 12 months that the company wants the committee to review.

DATES: The meeting will be held in October 1995. Biological companies may submit review requests for the October meeting before October 10, 1995.

ADDRESSES: Submit clinical hold review requests to Amanda B. Pedersen, FDA Chief Mediator and Ombudsman, Office of the Commissioner (HF–7), Food and Drug Administration, rm. 14–105, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3390.

FOR FURTHER INFORMATION CONTACT: Joy A. Cavagnaro, Center for Biologics Evaluation and Research (HFM–2), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0379.

SUPPLEMENTARY INFORMATION: FDA regulations in part 312 (21 CFR part 312) provide procedures that govern the use of investigational new drugs and biologics in human subjects. These regulations require that the sponsor of a clinical investigation submit an investigational new drug application (IND) to FDA outlining the proposed use of the investigational product. The IND must contain the study protocol, a summary of human and animal experience with the product, and information on the product's characterization, chemistry and pharmacology. FDA reviews an IND to help ensure the safety and rights of human subjects of research and to help ensure that the quality of any scientific evaluation of a drug is adequate to permit an evaluation of the product's efficacy and safety.

If FDA determines that a proposed or ongoing study may pose significant risks for human subjects or is otherwise seriously deficient, as discussed in the investigational new drug regulations, it may impose a clinical hold on the study. The clinical hold is one of FDA's primary mechanisms for protecting subjects who are involved in investigational new drug or biologic trials. A clinical hold is an order that FDA issues to a sponsor to delay a proposed investigation or to suspend an ongoing investigation. The clinical hold may be placed on one or more of the investigations covered by an IND. When a proposed study is placed on clinical hold, subjects may not be given the investigational drug or biologic as part of that study. When an ongoing study is placed on clinical hold, no new subjects may be recruited to the study and placed on the investigational drug or biologic, and patients already in the study should stop receiving therapy involving the investigational drug or biologic unless FDA specifically permits it.

FDA regulations in § 312.42 describe the grounds for the imposition of a clinical hold. When FDA concludes that there is a deficiency in a proposed or ongoing clinical trial that may be grounds for the imposition of a clinical hold order, ordinarily FDA will attempt to resolve the matter through informal discussions with the sponsor. If that attempt is unsuccessful, the agency may order a clinical hold.

A clinical hold is ordered by or on behalf of the director of the division that is responsible for review of the IND. The order identifies the studies under the IND to which the clinical hold applies and explains the basis for the action. The clinical hold order may be made by telephone or other means of rapid communication, or in writing. Irrespective of the 30-day time limit permitted by § 312.42(d), CBER policy provides that within 15 days of the notification of the clinical hold by telephone or other method of rapid communication, the sponsor will be provided with a written explanation of the basis for the clinical hold. In addition to providing a statement of reasons, this ensures that the clinical hold is recorded in CBER's management information system.

The clinical hold order specifies whether the sponsor may resume the affected investigation without prior notification by FDA once the deficiency has been corrected. If the order does not permit the resumption without notification, an investigation may resume only after the division director or his or her designee has notified the sponsor that the investigation may proceed. Resumption may be authorized by telephone or other means of rapid communication. If all investigations covered by an IND remain on clinical hold for 1 year or longer, FDA may place the IND on inactive status.

FDA regulations in § 312.48 provide dispute resolution mechanisms through which sponsors may request reconsideration of clinical hold orders. The regulations encourage the sponsor to attempt to resolve disputes directly with the review staff responsible for the review of the IND. If necessary, the sponsor may request a meeting with the review staff and management to discuss the clinical hold.

Over the years, drug sponsors have expressed a number of concerns about the clinical hold process, including concerns about the scientific and procedural adequacy of some agency actions. FDA undertook several initiatives to evaluate the consistency and fairness of the Center for Drug Evaluation and Research's (CDER's) practices in imposing clinical holds. First, CDER completed a centerwide review of clinical holds recorded in their management information system. While some differences in practice and procedure were discerned among

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