ADDRESSES: Submit written requests for single copies of the guideline entitled, ''Protocol Development Guideline for Clinical Effectiveness and Target Animal Safety Trials'' to the Communications and Education Branch (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1755. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on the guideline to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the guideline and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Larry Ventura, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1647.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of the guideline entitled, ''Protocol Development Guideline for Clinical Effectiveness and Target Animal Safety Trials'' prepared by CVM. The guideline is intended to be used by clinical investigators, study monitors, and sponsors, when designing investigations of effectiveness and target animal safety for animal drug approval and may be used when submitting the final reports of these trials. This guideline was written in response to a request by the animal health industry for guidance on facilitating protocol development and expediting CVM's review of the submitted protocols, and it should help sponsors to include all essential components of the study in the protocol. More uniform reports should allow a systematic, orderly review of the data by CVM. The goals of the protocol development guideline are to:

1. Suggest a uniform system for writing study protocols,

2. Provide a reference of essential items that should be considered for inclusion in a study protocol,

3. Facilitate the development of complete study protocol(s) by the author(s),

4. Design more user friendly protocols for investigator(s),

5. Enable FDA reviewers to evaluate study protocols more quickly and convey their comments in terms more easily understood by the sponsor, and

6. Reduce the number of essential revisions of study protocols.

The guideline offers a complete outline of the components necessary for a well-designed study so that CVM and industry have a common reference point. This uniform approach will facilitate the drafting of study reports by the sponsor and their subsequent review by CVM. The contents of this guideline are neither all inclusive nor will all items listed be applicable to all study protocols. It is the responsibility of the sponsor to ensure that the essential components of a study are included in their protocol. Guidelines state procedures or practices that may be useful to the persons to whom they are directed, but are not legal requirements. A person may follow the guideline or may choose to follow alternate procedures or practices. If a person chooses to use alternate procedures or practices, that person may wish to discuss the matter further with the agency to prevent an expenditure of money and effort on activities that may later be determined to be unacceptable to FDA.

Guidelines are generally issued under §§ 10.85(a) and 10.90(b)(21 CFR 10.85(a) and 10.90(b)). The agency is now in the process of revising §§ 10.85(a) and 10.90(b). Therefore, this guideline is not being issued under the authority of §§ 10.85(a) and 10.90(b). A guideline does not bind the agency, and it does not create or confer any rights, privileges, or benefits for or on any person. When a guideline states a requirement imposed by statute or regulation, however, the requirement is law and its force and effect are not changed in any way by virtue of its inclusion in the guideline.

Interested persons may, at any time, submit written comments on the guideline to the Dockets Management Branch (address above). FDA will consider these comments in determining whether further amendments to, or revisions of, the document are warranted. Two copies of any comments should be submitted, except that individuals may submit one copy, identified with the docket number found in brackets in the heading of this document. The guideline and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday, at the Dockets Management Branch.

Dated: March 16, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–7513 Filed 3–27–95; 8:45 am]

BILLING CODE 4160–01–F

Industry and Consumer Exchange Meeting Concerning FDA and APHIS Activities on a Potential Agreement With the European Union Related to Human and Animal Drug and Biological Product Information; Notice of Public Meeting

AGENCIES: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) and Animal and Plant Health Inspection Service (APHIS) are cosponsoring a public meeting with all persons interested in a potential agreement with the European Union that would facilitate the harmonization of good manufacturing practices (GMP's) and quality controls for human and animal drug and biological products and associated compliance and enforcement activities, and provide for the exchange and use of such information by the respective regulatory authorities. Such an agreement would enhance the goals of harmonizing the monitoring and enforcement standards of the GMP's and would facilitate international trade.

DATES: The industry and consumer exchange meeting will be held on Friday, March 31, 1995, 9 a.m. to 12 m.

ADDRESSES: The industry and consumer exchange meeting will be held at the Hubert H. Humphrey Bldg., Humphrey Auditorium, 200 Independence Ave. SW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Walter M. Batts, Office of Health Affairs (HFY–50), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4480 (Fax 301–443–0235).

Those persons interested in attending this meeting should Fax their registration, including name, firm, or organization name, address, and telephone number to Nathaniel L. Geary, Office of External Affairs, Food and Drug Administration (301–443–5153) or telephone 301–443–6776. There is no registration fee, but advance registration is requested. Additionally, if there are any individuals that wish to make a presentation at this meeting, advance notice is required.

SUPPLEMENTARY INFORMATION: The purpose of the public meeting is to provide information concerning FDA and APHIS activities with the European Union related to human and animal drug and biological product GMP's and quality controls, as well as to provide an opportunity to hear and address concerns from persons involved in these industries and persons representing consumer and other interests.

FDA and APHIS have been participating in bilateral Mutual Recognition Agreement talks. These talks are being led by the Office of the U.S. Trade Representative and the Department of Commerce and by representatives of the European Union. FDA and APHIS will meet with representatives from the European Union and its Member States from April 3 to April 5, 1995, in Brussels, Belgium to exchange information on their respective programs. During the Brussels meeting, U.S. industry will have the opportunity to present its experience with U.S. and European GMP and quality control programs.

Dated: March 24, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–7740 Filed 3–24–95; 3:14 pm]

BILLING CODE 4160–01–F

Investigational New Drugs; 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 Drug Evaluation and Research (CDER) has placed on certain investigational new drug trials. The committee was established as a 1-year experiment in August 1991. The committee met quarterly through 1992 and currently meets semiannually as a regular program. The committee last met in October 1994. FDA is inviting any interested drug company to use the confidential mechanism to submit to the committee for its review the name and number of any investigational new drug 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 June 1995. Drug companies may submit review requests for the June meeting before April 27, 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, 301–443–1306.

FOR FURTHER INFORMATION CONTACT: Deborah A. Wolf, Center for Drug Evaluation and Research (HFD–362), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1046.

SUPPLEMENTARY INFORMATION: FDA regulations at part 312 (21 CFR part 312) provide procedures that govern the use of investigational new drugs 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 drug. The IND must contain the study protocol, a summary of human and animal experience with the drug, and information about the drug's chemistry and pharmacology. FDA reviews an IND to help ensure the safety and rights of subjects and to help ensure that the quality of any scientific evaluation of drugs is adequate to permit an evaluation of the drug's efficacy and safety. An investigational new drug for which an IND is in effect is exempt from the premarketing approval requirements that are otherwise applicable and may be shipped lawfully for the purpose of conducting clinical investigations of that drug.

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 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 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, and patients already in the study should stop receiving therapy involving the investigational drug unless FDA specifically permits it.

FDA regulations at 21 CFR 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 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. In CDER, 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 hold applies and explains the basis for the action. The hold order may be made by telephone or other means of rapid communication, or in writing. Within 30 days of the imposition of the clinical hold, the division director provides the sponsor with a written explanation of the basis for the hold. Any sponsor who has not received a written explanation within 30 days should notify the division and request that it be issued. In addition to providing a statement of reasons, this ensures that the hold is recorded in CDER'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, 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 at 21 CFR 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, a sponsor may request a meeting with the review staff and management to discuss the 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's practices in imposing clinical holds. First, CDER completed a center-wide review of clinical holds recorded in the management information system. While some differences in practice and procedure were discerned among divisions, it appeared that the procedures specified in the regulations were, in general, being followed, and that 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