requested not to send pamphlets, maps, brochures or other printed material along with their application as these are difficult to photocopy. These materials, if submitted, will not be included in the review process. Each page of the application will be counted (excluding required forms and certifications) to determine the total length.

The project description should include all the information requirements described in the specific evaluation criteria outlined in the program announcement under Part III.C. The Administration for Children and Families Uniform Project Description in the application kit provides general requirements for these evaluation criteria (i.e., Objectives and Need for Assistance; Approach; Evaluation; Budget and Budget Justification).

B. Application Submission

1. Mailed applications postmarked after the closing date will be classified as late and will not be considered in the competition.

2. Deadline. Mailed applications shall be considered as meeting an announced deadline if they are either received on or before the deadline date or sent on or before the deadline date and received by ACF in time for the independent review to: U.S. Department of Health and Human Services, Administration for Children and Families, Office of Grants Management, Office of Child Support Enforcement, Attention: Mary Nash, 370 L'Enfant Promenade, S.W., 4th Floor West, Washington, D.C. 20447. Applicants must ensure that a legibly dated U.S. Postal Service postmark or a legibly dated, machine-produced postmark of a commercial mail service is affixed to the envelope/package containing the application(s).

To be acceptable as proof of timely mailing, a postmark from a commercial mail service must include the logo/emblem of the commercial mail service company and must reflect the date the package was received by the commercial mail service company from the applicant. Private Metered postmarks shall not be acceptable as proof of timely mailing. (Applicants are cautioned that express/overnight mail services do not always deliver as agreed). Express/overnight mail services should use the 901 D Street address instructions as shown below.)

Applications handcarried by applicants, applicant couriers, or by other representatives of the applicant using express/overnight mail services, will be considered as meeting an announced deadline if they are received on or before the deadline date, between the hours of 8:00 a.m. and 4:30 p.m., EST, addressed to the U.S. Department of Health and Human Services, Administration for Children and Families, Attention: Mary Nash, Office of Grants Management, Office of Child Support Enforcement, and delivered at ACF Mailroom, 2nd Floor (near loading dock), Aerospace Building, 901 D Street, S.W., Washington, D.C. 20024, between Monday and Friday (excluding Federal holidays). The address must appear on the envelope/package containing the application. ACF cannot accommodate transmission of applications by fax or through other electronic media. Therefore, applications transmitted to ACF electronically will not be accepted regardless of date or time of submission and time of receipt.

3. Late applications. Applications that do not meet the criteria above are considered late applications. ACF shall notify each late applicant that its application will not be considered in the current competition.

4. Extension of deadlines. ACF may extend an application deadline when circumstances such as acts of God (floods, hurricanes, etc.) occur, or when there are widespread disruption of the mail service, or in other rare cases. Determinations to extend or waive deadline requirements rest with ACF's Chief Grants Management Officer.

Dated: December 25, 1999.

David Gray Ross,

Commissioner, Office of Child Support Enforcement.

[FR Doc. 00–208 Filed 1–4–00; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99F–5522]

Food Irradiation Coalition c/o National Food Processors Association; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that The National Food Processors Association, on behalf of The Food Irradiation Coalition, has filed a petition proposing that the food additive regulations be amended to provide for the safe use of ionizing radiation for control of food-borne pathogens, and extension of shelf-life, in a variety of human foods up to a maximum irradiation dosage of 4.5 kilograys (kGy) for non-frozen and non-dry products, and 10.0 kGy for frozen or dry products.

FOR FURTHER INFORMATION CONTACT: Lane A. Highbarger, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3032.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 9M4697) has been filed by The National Food Processors Association on behalf of The Food Irradiation Coalition, 1350 I St. NW., Suite 300, Washington, DC 20005. The petition proposes that the food additive regulations in part 179 *Irradiation in the Production, Processing and Handling of Food* (21 CFR part 179) be amended to provide for the safe use of ionizing radiation for control of food-borne pathogens, and extension of shelf-life, in a variety of human foods up to a maximum irradiation dosage of 4.5 kGy for non-frozen and non-dry products, and 10.0 kGy for frozen or dry products, including: (1) Pre-processed meat and poultry; (2) both raw and pre-processed vegetables, fruits, and other agricultural products of plant origin; (3) certain multi-ingredient food products. The petition does not cover products composed in whole or in part of raw meat, poultry, or fish nor does it cover ''ready-to-eat'' fish products or ingredients made from fish.

The agency has determined under 21 CFR 25.32(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: December 20, 1999

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 00–108 Filed 1–4–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the year 2000 meetings of its clinical hold oversight committee, which reviews the clinical hold orders that the Center for Biologics Evaluation and Research (CBER) has placed on certain investigational biological product trials. For each meeting, FDA is inviting any interested biological product company to use this confidential mechanism to submit to the committee for its review the name and number of any investigational biological product trial placed on clinical hold during the past 12 months that the company wants the committee to review

DATES: The meetings will be held on February 10, 2000; May 11, 2000; August 10, 2000; and November 9, 2000. Biological product companies may submit review requests for the February meeting by January 20, 2000; for the May meeting by March 30, 2000; for the August meeting by June 29, 2000; and for the November meeting by September 28, 2000.

ADDRESSES: Submit clinical hold review requests to Steven H. Unger, FDA Acting Ombudsman, Office of the Commissioner (HF–7), 5600 Fishers Lane, rm. 14–105, Rockville, MD 20857, 301–827–3390.

FOR FURTHER INFORMATION CONTACT: Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: FDA's regulations in part 312 (21 CFR part 312) provide procedures that govern the use of investigational new drugs and biologics in human subjects. 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 order 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. Section 312.42 describes the grounds for ordering a clinical hold.

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 ordered on one or more of the investigations covered by an investigational new drug application (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.

When FDA concludes that there is a deficiency in a proposed or ongoing clinical trial that may be grounds for ordering a clinical hold, ordinarily FDA will attempt to resolve the matter through informal discussions with the sponsor. If that attempt is unsuccessful, a clinical hold may be ordered by or on behalf of the director of the division that is responsible for the review of the IND.

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.

CBER began a process to evaluate the consistency and fairness of practices in ordering clinical holds by instituting an oversight committee to review clinical holds (see 61 FR 1033, January 11, 1996). CBER held its first clinical hold oversight committee meeting on May 17, 1995, and plans to conduct further quality assurance oversight of the IND process. 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 the Center for Drug Evaluation and Research, and the FDA 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 FDA's scientific or procedural basis for the decision.

Requests for committee review of a clinical hold should be submitted to the FDA 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 FDA regulations and CBER policy.

The meetings of the oversight committee are closed to the public because committee discussions deal with confidential commercial information. Summaries of the committee deliberations, excluding confidential commercial information, may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. If the status of a clinical hold changes following the committee's review, the appropriate division will notify the sponsor.

For each meeting, FDA invites biological product companies to submit to the FDA Chief Mediator and Ombudsman the name and IND number of any investigational biological product trial that was placed on clinical hold during the past 12 months that they want the committee to review. Submissions should be made by January 20, 2000, for the February meeting; by March 30, 2000, for the May meeting; by June 29, 2000, for the August meeting; and by September 28, 2000, for the November meeting to Steven H. Unger, FDA Acting Ombudsman (address above).

Dated: December 28, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–109 Filed 1–4–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1094–N]

Medicare Graduate Medical Education Consortia Demonstration

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice announces the Medicare Graduate Medical Education (GME) Consortia demonstration, which will test how teaching hospitals and affiliated organizations respond to the incentive of shared direct GME payments. HCFA is interested in newly formed partnerships as well as already existing GME consortia. HCFA plans to conduct the demonstration with a limited number of consortia, to be chosen through a competitive