insurance from that employer and essential persons to contact. Based upon this information, Census will mail a questionaire to the employer. In order to assure high response rates, Census will follow-up with a second mailing at an acceptable interval, followed by a telephone call to collect data from those who have not responded by mail. For large organizational respondents with high burdens, such as State employers and very large firms, Census will, if needed, perform personal visits and do customized collection, such as, acceptance of data in computerized formats and use of special forms.

Estimated Annual Respondent Burden

Annual number of respondents	Estimated hours per respondent	Estimated total annual burden hours	Estimated annual cost to the government
33,839	.5	19,369	$7,000,000

Estimates of annual respondent burden are based upon experience from collection of the previous three MEPS—IC surveys.

Copies of these proposed collection plans and instruments can be obtained from the AHRQ Reports Clearance Officer (see above).

Dated: December 15, 1999.

John M. Eisenberg,

Director.

[FR Doc. 99–32942 Filed 12–20–99; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99F–5322]

United States Department of Agriculture, Food Safety and Inspection Service; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the United States Department of Agriculture, Food Safety and Inspection Service has filed a petition proposing that the food additive regulations be amended to increase the maximum dose of ionizing radiation permitted in the treatment of poultry products, include specific language intended to clarify the poultry products covered by the regulations, and remove the limitation that any packaging used during irradiation of poultry shall not exclude oxygen.

FOR FURTHER INFORMATION CONTACT: Rudaina H. Alrefai, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 100 C St. SW., Washington, DC 20204, 202–418–3034.

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 9M4696) has been filed by the United States Department of Agriculture, Food Safety and Inspection Service, 300 12th St. SW., rm. 112, Washington, DC 20250. The petition proposes to amend the food additive regulations in § 179.26 *Ionizing radiation for the treatment of food* (21 CFR 179.26) in item 6. of the table in paragraph (b) to: (1) Increase the maximum dose of ionizing radiation permitted in the treatment of poultry products (2) include specific language intended to clarify the poultry products covered by the regulations and (3) remove the limitation that any packaging used during irradiation of poultry shall not exclude oxygen.

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 3, 1999.

Alan M. Rulis,

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

[FR Doc. 99–33004 Filed 12–20–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–5125]

Draft Guidance on the Labeling for Over-the-Counter Sample Collection Systems for Drugs of Abuse Testing; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Guidance on Labeling for Over-the-Counter Sample Collection Systems for Drugs of Abuse Testing.'' This guidance is neither final nor is it in effect at this time. This guidance provides labeling recommendations for over-the-counter sample collection systems for drugs of abuse testing and is being issued as a result of FDA's proposed reclassification of over-the-counter sample collection systems for drugs of abuse testing as class I restricted devices.

DATES: Submit written comments concerning this draft guidance by March 22, 2000.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance. Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled ''Guidance on Labeling for Over-the-Counter Sample Collection Systems for Drugs of Abuse Testing'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818.

Submit written comments on this draft guidance to the Dockets Management Branch, (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Joseph Hackett, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3084.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 5, 1998 (63 FR 10792), FDA published a proposed rule that would reclassify over-the-counter (OTC) sample collection systems for drugs of abuse testing from class III (premarket approval) to class I (general controls),

and would exempt them from the premarket notification (510(k)) and current good manufacturing practice (CGMP) requirements. The proposal would also restrict these devices under section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(e)) to require the following: (1) The laboratory test(s) incorporated into these systems would be required to have been cleared, approved, or otherwise recognized by FDA as accurate and reliable for laboratory use; (2) the laboratory performing the underlying test(s) must be able to reliably perform the necessary screening and confirmatory tests; and (3) the samples must be adequately identified to avoid mix-ups and the test sample collection system must be accurately labeled so that consumers can readily use it. The draft guidance will help manufacturers meet this third criterion if the regulation becomes final and also can be used by manufacturers currently marketing these products under FDA's Interim Policy regarding ''Parents' Access to Tests for Drugs of Abuse.'' This draft guidance also addresses the need to provide consumers with access to professional assistance in interpreting/understanding test results and counseling referrals.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on labeling of over-the-counter sample collection systems for drugs of abuse testing. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive the draft guidance entitled ''Guidance on Labeling for Over-the-Counter Sample Collection Systems for Drugs of Abuse Testing'' via your fax machine; call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (1154) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer. Updated on a regular basis, the CDRH home page includes the draft guidance entitled ''Guidance on Labeling for Over-the-Counter Sample Collection Systems for Drugs of Abuse Testing,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. ''Guidance on Labeling for Over-the-Counter Sample Collection Systems for Drugs of Abuse Testing'' will be available at http://www.fda.gov/cdrh/ggpmain.html#docs.

IV. Paperwork Reduction Act of 1995

The information collection provisions referred to in this guidance have been approved under OMB control number 0910–0368. This approval expires April 30, 2001. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

V. Comments

Interested persons may, on or before March 22, 2000, submit to Dockets Management Branch (address above) written comments regarding this draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 10, 1999.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 99–33002 Filed 12–20–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Establishment

Pursuant to the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), the Director, National Institutes of Health (NIH), announces the establishment of the PubMed Central National Committee (Committee).

This Committee will advise the Director, NIH, the Director, National Library of Medicine, and the Director, National Center for Biotechnology Information, on the content and operation of the PubMed Central repository. The Committee will establish criteria to certify groups submitting materials to the system, monitoring the operation of the system, and ensuring that PubMed Central evolves and remains responsive to the needs of researchers, publishers, librarians and the general public.

Unless renewed by appropriate action prior to its expiration, the charter for the PubMed Central National Advisory Committee will expire two years from the date of establishment.

Dated: December 15, 1999.

Harold Varmus,

Director, National Institutes of Health.

[FR Doc. 99–32966 Filed 12–20–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Research Resources Special Emphasis Panel Biomedical Research Technology.

Date: January 5, 2000.