(HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product ULTRAVIST® (iopromide). ULTRAVIST® is indicated for intra-arterial digit subtraction and visceral angiography; cerebral, peripheral, and coronary arteriography; left ventriculography, aortography, peripheral venography, and contrast-enhanced, computed tomographic imaging of the head and body, and excretory urography. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ULTRAVIST® (U.S. Patent No. 4,364,921) from Schering Aktiengesellschaft, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated August 18, 1995, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ULTRAVIST® represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for ULTRAVIST® is 2,518 days. Of this time, 1,353 days occurred during the testing phase of the regulatory review period, while 1,165 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* June 19,1988. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on June 19, 1988.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act:* March 2, 1992. FDA has verified the applicant's claim that the new drug application (NDA) for ULTRAVIST® (NDA 20–220) was initially submitted on March 2, 1992.

3. *The date the application was approved:* May 10, 1995. FDA has verified the applicant's claim that NDA 20–220 was approved on May 10, 1995.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,825 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before December 26, 1995, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before April 23, 1996, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 5, 1995.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 95–26501 Filed 10–24–95; 8:45 am]

BILLING CODE 4160–01–F

Characterization of Biological/Biotechnology Pharmaceutical Products; Notice of Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop on Characterization of Biological/Biotechnology Pharmaceutical Products. The workshop will discuss the types of data that are necessary to characterize biological/biotechnology pharmaceutical products to assure their safety, identity, purity, potency, quality, and consistency. Discussions will address the current abilities and limitations of analytical technologies for characterization of biotechnology products.

DATES: The public workshop, to include plenary and technical breakout sessions, will be held on December 11, 12, and 13, 1995, from 8 a.m. to 5 p.m. Participants may pick up their information packages and badges for admission to the sessions beginning each morning at approximately 7:30 a.m.

ADDRESSES: The public workshop will be held at the Omni Shoreham Hotel, 2500 Calvert St. NW., Washington, DC 20008. There is no registration fee for this workshop, but advance registration is requested. Interested parties are encouraged to register early because space is limited.

FOR FURTHER INFORMATION CONTACT:

Regarding information on registration and other logistical matters contact: Dawn Apple, KRA Corp., 1010 Wayne Ave., suite 850, Silver Spring, MD 20910, 301–495–1591, or FAX 301–495–2919.

Regarding information on this document contact: Rosanna L. Harvey, Center for Biologics Evaluation and Research (HFM–20), 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0377, or FAX 301–827–0440.

SUPPLEMENTARY INFORMATION: FDA recognizes that there have been technology developments in process

control and new methodologies that can be applied to product characterization and is interested in exploring with the public and industry whether biological/biotechnology pharmaceutical products can be well characterized. FDA intends to develop a definition for well characterized biological/biotechnology pharmaceutical products manufactured using biotechnology.

The goals of this meeting are to: (1) Discuss those analytical techniques, process validations, and parameters that are critical in the characterization of biological/biotechnology pharmaceutical products to assure safety, identity, purity, potency, quality, and consistency; and (2) develop a functional definition for well characterized biological/biotechnology pharmaceutical products. The information generated at the workshop may be used by FDA in developing future scientific and regulatory policies.

Dated: October 20, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–26500 Filed 10–24–95; 8:45 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration

Agency Forms Undergoing Paperwork Reduction Act Review

Periodically, the Health Resources and Services Administration (HRSA) publishes a list of information collection requests under review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the HRSA Reports Clearance Office on (301)–443–1129.

The following request has been submitted to the Office of Management and Budget for review:

1. Data Collection and Reporting Requirements for Healthy Start—Extension and Revision—Patient records and aggregate data are being collected from Healthy Start grantees in order to evaluate the overall effectiveness of the initiative and the value of specific interventions for varying groups of target women. A number of minor revisions have been proposed based on consultations with grantees regarding availability and utility of the data. Burden estimates are as follows:

Type of report	No. of respondents	Responses per respondent	Average burden per response (hrs)	Total burden hours
Patient Data	15	4	80	4,800
Midyear Reports	15	1	5	75
Aggregate Reports	15	1	40	600

Estimated Total Annual Burden: 5,475 hours.

Written comments and recommendations concerning the proposed information collections should be sent within 30 days of this notice to: Allison Eydt, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: October 20, 1995.

J. Henry Montes,

Associate Administrator for Policy Coordination.

[FR Doc. 95–26496 Filed 10–24–95; 8:45 am]

BILLING CODE 4160–15–P

National Institutes of Health

National Cancer Institutes; Notice of Closed Meetings

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 meetings of the National Cancer Institutes Initial Review Group:

Agenda/Purpose: To review and evaluate grant applications.

Committee Name: Subcommittee F—Manpower and Training.

Date: November 8–10, 1995.

Time: 8 a.m.

Place: The Holiday Inn Georgetown, 2101 Wisconsin Ave., N.W., Washington, D.C. 20007.

Contact Person: Mary Bell, Ph.D., 6130 Executive Blvd., Room 611A, Bethesda, MD 20892, Telephone: 301–496–7978.

Committee Name: Subcommittee G—Education.

Date: November 14–15, 1995.

Time: 8 a.m.

Place: The Holiday Inn Georgetown, 2101 Wisconsin Ave., N.W., Washington, D.C. 20007.

Contact Person: Neil B. West, Ph.D., 6130 Executive Blvd., Room 611D, Bethesda, MD 20892, Telephone: 301–402–2785.

Committee Name: Subcommittee C—Basic and Preclinical.

Date: December 4–6, 1995.

Time: December 4–7:30 p.m., December 5–6, 1995, 8 a.m.

Place: Ramada Inn, 8400 Wisconsin Ave., Bethesda, MD 20814.

Contact Person: Virginia Wray, Ph.D., 6130 Executive Plaza, Room 635D, Bethesda, MD 20892, Telephone: 301–496–9236.

Committee Name: Subcommittee B—Comprehensive.

Date: December 7–8, 1995.

Time: 8:30 a.m.

Place: Ramada Inn, 8400 Wisconsin Ave., Bethesda, MD 20814.

Contact Person: Dr. David E. Maslow, 6130 Executive Blvd., Room 643A, Bethesda, MD 20892, (301) 496–2330.

The meetings will be closed in accordance with the provisions set forth in sec. 552b(c)(4) and 552(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which could constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Numbers: 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control.)

Dated: October 18, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95–26384 Filed 10–24–95; 8:45 am]

BILLING CODE 4140–01–M

National Cancer Institute; Notice of Closed Meetings

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 meetings of the National Cancer Institute Special Emphasis Panel (SEP):

Name of SEP: Developmental Therapeutics.

Date: November, 13. 1995.

Time: 9 a.m.

Place: 6130 Executive Blvd., Conference Room F, Rockville, MD 20852.

Contact Person: Lalita Palekar, Ph.D., Scientific Review Administrator, National