collaborating countries. Research collaboration may include other industrialized nations in addition to the US. Substantial emphasis will be placed upon chronic disease prevention and the control of injuries. A successful program will allow the accumulated knowledge and experience of US environmental and occupational health experts to be available to assist and work with their colleagues on a global basis in order to address common global problems.

The meeting will be closed to the public in accordance with provisions set forth in 5 U.S.C. 552b(c) (4) and (6), and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Public Law 92–463.

Contact Person for More Information: Pervis C. Major, Ph.D., Health Science Administrator, Office of Extramural Coordination and Special Projects, Office of the Director, National Institute for Occupational Safety and Health, CDC, 1095 Willowdale Road, Morgantown, West Virginia 26505, telephone 304/285–5979 or 404/639–2535.

Dated: July 3, 1996.

Nancy C. Hirsch,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 96–17525 Filed 7–9–96; 8:45 am]

BILLING CODE 4163–18–M

Citizens Advisory Committee on Public Health Service Activities and Research at Department of Energy (DOE) Sites: Savannah River Site Health Effects Subcommittee and Savannah River Site Environmental Dose Reconstruction Project—Phase II Public Workshop: Meetings

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Agency for Toxic Substances and Disease Registry (ATSDR) and the Centers for Disease Control and Prevention (CDC), announce the following meetings.

Name: Citizens Advisory Committee on Public Health Service Activities and Research at DOE Sites: Savannah River Site Health Effects Subcommittee (SRS).

Times and Dates: 8:30 a.m.–5:15 p.m., July 25, 1996. 8:30 a.m.–12 noon, July 26, 1996.

Place: Holiday Inn Coliseum, 630 Assembly Street, Columbia, South Carolina 29201, telephone 803/799–7800, FAX 803/252–5909.

Status: Open to the pubic, limited only by the space available. The meeting room accommodates approximately 50 people.

Background: Under a Memorandum of Understanding (MOU) signed in December 1990 with DOE, the Department of Health and Human Services (HHS) has been given the responsibility and resources for conducting analytic epidemiologic investigations of residents of communities in the vicinity of DOE facilities, workers at DOE facilities, and other persons potentially exposed to radiation or to potential hazards from non-nuclear energy production use. HHS delegated program responsibility to CDC.

In addition, an MOU was signed in October 1990 and renewed in November 1992 between ASTDR and DOE. The MOU delineates the responsibilities and procedures for ATSDR's public health activities at DOE sites required under sections 104, 105, 107, and 120 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or ''Superfund''). These activities include health consultations and public health assessments at DOE sites listed on, or proposed for, the Superfund National Priorities List and at sites that are the subject of petitions from the public; and other health-related activities such as epidemiologic studies, health surveillance, exposure and disease registries, health education, substance-specific applied research, emergency response, and preparation of toxicological profiles.

Purpose: This subcommittee is charged with providing advice and recommendations to the Director, CDC, and the Administrator, ATSDR, regarding community, American Indian Tribes, and labor concerns pertaining to CDC's ATSDR's public health activities and research at respective DOE sites. Activities shall focus on providing a forum for community, American Indian Tribal, and labor interaction and serve as a vehicle for community concern to be expressed as advice and recommendations to CDC and ATSDR.

Matters to be Discussed: Agenda items include: presentations from the National Center for Environmental Health (NCEH), the National Institute for Occupational Safety and Health, and the Agency for Toxic Substances and Disease Registry on the progress of current studies; presentation on environmental monitoring; an update from the Radiological Assessments Corporation; and updates on the membership and the workgroup report.

Agenda items are subject to change as priorities dictate.

Name: Savannah River Site Environmental Dose Reconstruction Project—Phase II: Public Workshop.

Time and Date: 7 p.m.–9 p.m., July 25, 1996.

Place: Holiday Inn Coliseum, 630 Assembly Street, Columbia, South Carolina 29201, telephone 803/799–7800, FAX 803/252–5909.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

Purpose: The Savannah River Site (SRS) Dose Reconstruction Project supports research which evaluates past releases of radioactive materials and chemicals from the SRS to the surrounding environment. The Project has already undergone a first phase. Phase I involved searching the site to identify and retrieve important documents to be used for dose reconstruction. Phase II will use this information to calculate chemical and radiological source terms and identify possible intake pathways (eating, drinking, and inhalation) for people who have lived in the SRS area. This workshop will focus on the identification and evaluation of environmental data to support dose reconstruction. Public input and the promise to provide clear and easily obtained sources of information are important parts of this study. Individuals with information of possible value to the study are encouraged to attend.

Agenda items are subject to change as priorities dictate.

Contact Persons for More Information: Paul G. Renard or Nadine Dickerson, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 4770 Buford Highway, NE, (F–35), Atlanta, Georgia 30341–3724, telephone 770/488–7040, FAX 770/488–7044.

Due to difficulty in location of meeting facility, this notice is being published less than 15 days prior to the meeting.

Dated: July 3, 1996.

John C. Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 96–17524 Filed 7–9–96; 8:45 am]

BILLING CODE 4163–18–M

Food and Drug Administration

[Docket No. 96P–0083]

Determination that Acetaminophen and Codeine Tablets USP, 325 Milligrams (mg)/45 mg, was not Withdrawn from Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that acetaminophen and codeine phosphate tablets USP, 325 mg/45 mg, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow abbreviated new drug applications (ANDA's) for acetaminophen and codeine phosphate tablets USP, 325 mg/45 mg to be approved.

FOR FURTHER INFORMATION CONTACT: Christine F. Rogers, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress passed into law the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions,

show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the listed drug, which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDA's do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments included what is now section 505(j)(6) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(j)(6)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)). Regulations also provide that the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (§ 314.161(a)(1) (21 CFR 314.161(a)(1))). FDA may not approve an ANDA that does not refer to a listed drug.

Mikart Inc. (Mikart) submitted a citizen petition dated February 27, 1996 (Docket No. 96P–0083/CP1), under 21 CFR 10.30(b) and 314.122(a), requesting that the agency determine whether acetaminophen and codeine phosphate tablets USP, 325 mg/45 mg, was withdrawn from sale for reasons of safety or effectiveness and, if the agency determines that the drug was not withdrawn from sale for reasons of safety or effectiveness, to keep the drug in the ''Approved Drug Products with Therapeutic Equivalence Evaluations.'' Acetaminophen and codeine phosphate tablets USP, 325 mg/45 mg, is the subject of approved ANDA 85–363 held by KV Pharmaceuticals (KV). KV obtained approval of the ANDA on August 23, 1977, but has never marketed the product. FDA has determined, for purposes of §§ 314.161 and 314.162(c), that never marketing an approved drug product is equivalent to withdrawing the drug for sale.

FDA has reviewed its records and, under § § 314.161 and 314.162(c), has determined that acetaminophen and codeine phosphate tablets USP, 325 mg/45 mg, was not withdrawn from sale for reasons of safety or effectiveness and will continue to list acetaminophen and codeine phosphate tablets USP, 325 mg/45 mg, in the ''Discontinued Drug Product List'' contained in the ''Approved Drug Products with Therapeutic Equivalence Evaluations.'' The ''Discontinued Drug Product List'' lists, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDA's that refer to acetaminophen and codeine phosphate tablets USP, 325 mg/45 mg, may be approved by the agency.

Dated: July 2, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–17472 Filed 7–9–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96M–0201]

BARD Diagnostic Sciences, Inc.; Premarket Approval of BARD® BTA® Test

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by BARD Diagnostic Sciences, Inc., Redmond, WA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the BARD® BTA® Test. After reviewing the recommendation of the Immunology Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of November 29, 1995, of the approval of the application.

DATES: Petitions for administrative review by August 9, 1996.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Peter E. Maxim, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1293.

SUPPLEMENTARY INFORMATION: On June 6, 1994, BARD Diagnostic Sciences, Inc., Redmond, WA 98052, submitted to CDRH an application for premarket approval of BARD® BTA® Test. The BARD® BTA® rapid latex agglutination test is an in vitro device intended for the qualitative measurement of Bladder Tumor Associated Analytes in human urine to aid in the management of bladder cancer patients.

On September 21, 1995, the Immunology Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On November 29, 1995, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b)(21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before August 9, 1996, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this