

SUPPLEMENTARY INFORMATION: You may call 202-452-3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Web site at <http://www.bog.frb.fed.us> for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Dated: December 5, 1997.

William W. Wiles,

Secretary of the Board.

[FR Doc. 97-32394 Filed 12-5-97; 4:27 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency For Health Care Policy And Research

Contract Review Meeting

In accordance with Section 10(a) of the Federal Advisory Committee Act (5 U.S.C. Appendix 2), the Agency for Health Care Policy and Research (AHCPR) announces the following technical review committee to meet during the month of December 1997:

Name: Technical Review Committee for the AHCPR User Liaison Program Dissemination Support Contracts.

Date and Time: December 17-18, 1997, 9:00 a.m.-5:00 p.m.

Place: Agency for Health Care Policy and Research, Executive Office Building, 6th Floor (East Wing) Conference Rooms, Room 2 on December 17; Room 1 on December 18, 2101 East Jefferson Street, Rockville, MD 20852.

This meeting will be closed to the public.

Purpose: The Technical Review Committee's charge is to provide, on behalf of the AHCPR Contracts Review Committee, recommendations to the Administrator, AHCPR, regarding the technical merit of contract proposals submitted in response to a specific Request for Proposals for the User Liaison Program (ULP) Dissemination Support contracts.

The purpose of these contracts is to provide for the timely and effective transmission of relevant health services research findings and related descriptive and programmatic information to a broad spectrum of selected public and private users of health services research to assist them in managing more effectively the problems and issues that confront them with respect to the design, delivery, quality, evaluation, and financing of health services. In performance of these contracts, the contractors shall plan, develop, and conduct workshops, seminars, and meetings and prepare research syntheses, background papers, or technical assistance documents on health policy issues for

selected target audiences. The target audiences of users of health services research include state and local officials; health care consumers, purchasers, plans, practitioners, and policymakers (including Federal executive branch officials). In planning and conducting workshops, the contractors will be responsible for not only conducting comprehensive and objective assessments of relevant information, but also for effectively presenting such information in a manner which is tailored to the particular needs of the selected target audience(s).

Agenda: The Committee meeting will be devoted entirely to the technical review and evaluation of contract proposals submitted in response to the above referenced Request for Proposals. The Administrator, AHCPR, has made a formal determination that this meeting will not be open to the public. This action is necessary to protect the free and full exchange of views in the contract evaluation process and safeguard confidential proprietary information, and personal information concerning individuals associated with the proposals that may be discussed during the meeting. This action is taken in accordance with section 10(d) of the Federal Advisory Committee Act, 5 U.S.C., Appendix 2, 5 U.S.C. 552b(c)(6), 41 CFR Section 101-6.1023 and Department procurement regulations, 48 CFR section 315.604(d).

Anyone wishing to obtain information regarding this meeting should contact Marcia Clark, User Liaison Program, Center for Health Information Dissemination, Agency for Health Care Policy and Research, 2101 East Jefferson Street, Suite 401, Rockville, Maryland 20852, 301/594-6668.

Dated: December 3, 1997.

John M. Eisenberg,

Administrator.

[FR Doc. 97-32281 Filed 12-9-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee; Science Board to the Food and Drug Administration; Formation of a Subcommittee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the formation of a subcommittee of the Science Board to the Food and Drug Administration (Science Board). The subcommittee entitled "Subcommittee for Center for Biologics Evaluation and Research Review" has been established to address scientific issues related to the research programs conducted by the FDA's Center for Biologics Evaluation and Research. The subcommittee's findings will be presented to the

Science Board for full public discussion at a future meeting.

FOR FURTHER INFORMATION CONTACT:

Susan K. Meadows, Office of Science (HF-32), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3340.

SUPPLEMENTARY INFORMATION: FDA is announcing the formation of a subcommittee of the Science Board. This subcommittee has been established to address issues related to the scientific quality, mission relevance, and scientific management and leadership of the research programs conducted by FDA's Center for Biologics Evaluation and Research. The subcommittee will hold its meeting(s) over the next 3 to 4 months to collect information on biologics research programs, to conduct an external peer review of biologics research for quality and relevance, and to assess an annual programmatic prioritization model. The subcommittee's findings will be presented to the Science Board for full public discussion at a future meeting that will be announced in the **Federal Register** prior to the meeting. This notice is issued under the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92-463 (5 U.S.C. app. 2)).

Dated: December 4, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97-32275 Filed 12-9-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee; Science Board to the Food and Drug Administration; Formation of a Subcommittee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the formation of a subcommittee of the Science Board to the Food and Drug Administration (Science Board). The subcommittee entitled "Board of Scientific Counselors" has been established to address scientific issues related to the research programs conducted by the Food and Drug Administration. The subcommittee's findings will be presented to the Science Board for full public discussion at future meetings.

FOR FURTHER INFORMATION CONTACT:

Susan K. Meadows, Office of Science

(HF-32), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD, 20857, 301-827-3340.

SUPPLEMENTARY INFORMATION: FDA is announcing the formation of a subcommittee of the Science Board. The subcommittee has been established to address issues related to the scientific quality, mission relevance, and scientific management and leadership of research programs conducted by FDA. The subcommittee will meet several times over the next 2 years to collect and review information on FDA's scientific research programs and to discuss a validated process for a coordinated, external, scientific peer review of the agency's research programs. The subcommittee's findings will be presented to the Science Board for full public discussion at future meetings that will be announced in the **Federal Register** prior to the meetings. This notice is issued under the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92-463 (5 U.S.C. app.2)).

Dated: December 4, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97-32276 Filed 12-9-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97F-0504]

The Goodyear Tire and Rubber Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the Goodyear Tire and Rubber Co. has filed a petition proposing that the food additive regulations be amended to provide for the expanded safe use of butylated reaction product of *p*-cresol and dicyclopentadiene for use as an antioxidant in acrylonitrile/butadiene/styrene copolymers in contact with food.

FOR FURTHER INFORMATION CONTACT: Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFS-205), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3086.

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 8B4561) has been filed by

The Goodyear Tire and Rubber Co., c/o Keller and Heckman LLP, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposes to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to provide for the expanded safe use of butylated reaction product of *p*-cresol and dicyclopentadiene for use as an antioxidant in acrylonitrile/butadiene/styrene copolymers in contact with food.

The agency has determined under 21 CFR 25.32(i) that this action is of the 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 2, 1997.

Alan M. Rulis,

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

[FR Doc. 97-32358 Filed 12-9-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M-0501]

Abbott Laboratories; Premarket Approval of IMx® PSA and AxSYM® PSA Assays

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the supplemental application by Abbott Laboratories, Diagnostics Div., Abbott Park, IL, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the IMx® PSA and AxSYM® PSA assay. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of August 7, 1997, of the approval of the supplemental application.

DATES: Petitions for administrative review by January 9, 1998.

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 November 2, 1994, Abbott Laboratories, Diagnostics Div., Abbott Park, IL 60064, submitted to CDRH a supplemental application for premarket approval of IMx® PSA and AxSYM® PSA assays. The devices are microparticle enzyme immunoassays (MEIA) for the quantitative measurement of Prostate Specific Antigen (PSA) in human serum as an aid in the detection of prostate cancer when used in conjunction with digital rectal exam (DRE) in men aged 50 years or older. Prostatic biopsy is required for diagnosis of cancer.

In accordance with the provisions of section 515(c)(2) of the act (21 U.S.C. 360e(c)(2)) as amended by the Safe Medical Devices Act of 1990, this premarket approval application (PMA) was not referred to the Immunology Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

On August 7, 1997, CDRH approved the supplemental application by a letter to the applicant from the Deputy Director of Clinical and Review Policy, 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 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 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 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