(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

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 January 9, 1998, 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 document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: October 31, 1997.

Joseph A. Levitt,

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

[FR Doc. 97–32216 Filed 12–9–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–320]

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Reinstatement, without change, of a previously approved collection for which approval has expired; *Title of Information Collection:* Corrective Action Plan (Medicaid Eligibility Quality Control); *Form No.:* HCFA–320; *Use:* Medicaid eligibility quality control (MEQC) is a State-administered system designed to improve the management of the Medicaid program and reduce the level of misspent Medicaid funds. Each month, States select a sample of Medicaid cases from their inventory of eligible cases and conduct QC reviews to determine the accuracy of the eligibility determinations. This Corrective Action Plan allows HCFA to determine the types of corrective actions used by States. Sound and effective corrective actions used by one State to correct causes of errors and reduce erroneous Medicaid payments are shared with other States experiencing the same types of error-causing problems. *Frequency:* Annually; *Affected Public:* State, Local or Tribal Government; *Number of Respondents:* 51; *Total Annual Responses:* 51; *Total Annual Hours:* 20,400.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Attention: John Rudolph, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: December 2, 1997

John P. Burke III,

HCFA Reports Clearance Officer, Division of HCFA Enterprise Standards, Health Care Financing Administration.

[FR Doc. 97–32320 Filed 12–9–97; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Availability of the HRSA Competitive Grants Preview

Correction

In notice document 97–26645 appearing on page 52905 of the issue on Thursday, October 9, 1997, make the following correction:

On page 52905, in the second column under the heading ''Centers of Excellence (COE)'' in the sixth paragraph labeled as ''Estimated Amount of This Competition,'' the amount should read ''$1,500,000.''

Dated: December 3, 1997.

Claude Earl Fox,

Acting Administrator.

[FR Doc. 97–32277 Filed 12–9–97; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Final Review Criteria for Grants for the National Research Service Awards: Primary Care Research for Fiscal Year 1998

The Health Resources and Services Administration (HRSA) National Research Service Awards: Primary Care Research (NRSA) institutional training grants (T32) are provided to accredited public or private nonprofit schools of medicine, osteopathy, dentistry, or a public or private nonprofit hospital or other entity which is affiliated with an entity that has received grants or contracts under section 747, 748, or 749 of the PHS Act, agrees to use the funding for research in primary medical care, and is located in a State. The NRSA program is authorized by Title IV, Section 487(d)(3)(A) of the Public Health Service Act.

A notice was published in the **Federal Register** at 62 FR 49521 on September 22, 1997, for review criteria for the above-referenced program. No comments were received within the 30 day comment period. Therefore, the review criteria remain as proposed.

Final Review Criteria

The following criteria are for National Research Service Awards in primary care research: