DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99F–2908]

The Goodyear Tire & 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 & Rubber Co. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of piperylene/2-methyl-2-butene/alpha-methylstyrene terpolymers for use in the preparation of can end cements intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

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 9B4685) has been filed by The Goodyear Tire & 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 § 175.300 *Resinous and polymeric coatings* (21 CFR 175.300) to provide for the safe use of piperylene/2-methyl-2-butene/alpha-methylstyrene terpolymers for use in the preparation of can end cements intended for use 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: August 12, 1999.

Laura M. Tarantino,

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

[FR Doc. 99–22719 Filed 8–31–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Feed Safety and Compliance With Animal Protein Prohibited in Ruminant Feed Rules Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) in cooperation with the California Department of Food and Agriculture (CDFA) and the Association of American Feed Control Officials (AAFCO), is announcing a public workshop for training regulatory officials and the feed industry. The workshop is designed to increase participants' understanding of the regulatory changes that affect the feed industry. The topics to be discussed relate to feed safety and include the animal protein in ruminant feed rule, veterinary feed directives, medicated feed good manufacturing practices, feed contamination, and antibiotic drug resistance.

Date and Time: The workshop will be held on September 28, 1999, from 8 a.m. to 5 p.m., and on September 29, 1999, from 8:30 a.m. to 3:30 p.m.

Location: The workshop will be held at the Delta King Hotel, 1000 Front St., Sacramento, CA, 916–444–5464. Persons needing hotel rooms must request the special rate for the AAFCO/CDFA workshop. A special rate is available until September 7, 1999.

Contact: For further information including a registration form: Steve Wong, Branch Chief, CDFA, 1220 N St., rm. A–472, Sacramento, CA 95814–5621, 916–654–0574, FAX 916–653–2407,

For general information: Karen L. Robles, Food and Drug Administration, 801 I St., Sacramento, CA 95814, 916–498–6400, ext. 14.

Registration: Advanced registration is required. Please register on or before September 10, 1999. There is a $50 registration fee which you should make payable to the Association of American Feed Control Officials (AAFCO). The registration fee will cover the cost of the facility. Send your registration fee and completed registration form to Feed Safety/BSE Training, c/o CDFA, Attn. Office Supervisor, Feed Inspection Program, 1220 N St., rm. A-472, Sacramento, CA 95814–5621. Space is limited, therefore, you are encouraged to register early.

If you need special accommodations due to a disability, please contact Steve Wong at least 7 days in advance.

Dated: August 25, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–22680 Filed 8–31–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Neurological Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Neurological Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 16, 1999, 11 a.m. to 6 p.m., and September 17, 1999, 8:30 a.m. to 3:30 p.m.

Location: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

Contact Person: Janet L. Scudiero, Center for Devices and Radiological Health (CDRH) (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1184, ext. 176, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12513. Please call the Information Line or access the World Wide Web at ''http://www.fda.gov/cdrh/upadvmtg.html'' for up-to-date information on this meeting.

Agenda: On September 16, 1999, the committee will discuss and make recommendations on: (1) The draft guidance entitled ''Guidance Document for Dura Substitute Devices,'' and (2) the classification of processed human dura mater. FDA notes that the guidance entitled ''Guidance for the Preparation of a Premarket Notification Application for Processed Human Dura Mater,'' which related to the classification of processed human dura mater, became effective on July 31, 1999.

On September 17, 1999, the committee will discuss and make recommendations on: (1) The draft guidance entitled ''Guidance Document

for Neurological Embolization Devices,'' and (2) the reclassification of the totally implanted spinal cord stimulator. Single copies of the guidance and the draft guidances are available to the public by calling 1–800–899–0381 or 301–827–0111 and requesting CDRH Facts-on-Demand by assigned document number, or the documents may be obtained on the Internet at the CDRH website as follows: ''Guidance Document for Dura Substitute Devices,'' Facts-on-Demand document number 1152, or ''http://www.fda.gov/cdrh/ode/1152.pdf''; ''Guidance for the Preparation of a Premarket Notification Application for Processed Human Dura Mater,'' Facts-on-Demand document number 054, or ''http://www.fda.gov/cdrh/ode/054.pdf''; and ''Guidance Document for Neurological Embolization Devices,'' Facts-on-Demand document number 1151, or ''http://www.fda.gov/cdrh/ode/1151.pdf''.

Procedure: On September 16, 1999, from 11 a.m. to 6 p.m., and on September 17, 1999, from 8:30 a.m. to 3:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 8, 1999. Oral presentations from the public will be scheduled on September 16, 1999, between approximately 12 noon and 12:30 p.m. for the discussion of the draft guidance entitled ''Guidance Document for Dura Substitute Devices'' and between approximately 3:45 p.m. and 4:15 p.m. and 5 p.m. and 5:30 p.m. for the classification of processed human dura mater. On September 17, 1999, oral presentations from the public will be scheduled between approximately 9:45 a.m. and 10:15 a.m. for the discussion of the draft guidance entitled ''Guidance Document for Neurological Embolization Devices'' and between approximately 12:15 p.m. and 12:45 p.m. and 2:30 p.m. and 3 p.m. for the reclassification of the totally implanted spinal cord stimulator. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 8, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On September 17, 1999, from 8 a.m. to 8:30 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information regarding pending and future FDA issues. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)). Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 25, 1999.

Linda Suydam,

Senior Associate Commissioner.

[FR Doc. 99–22713 Filed 8–27–99; 10:49 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2445]

Draft Guidance for Industry on Clinical Considerations for Accelerated and Traditional Approval of Antiretroviral Drugs Using Plasma HIV RNA Measurements; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Clinical Considerations for Accelerated and Traditional Approval of Antiretroviral Drugs Using Plasma HIV RNA Measurements.'' The draft guidance is intended to assist pharmaceutical sponsors in the development of antiretroviral drugs and to serve as a focus for continued discussion among the agency, the public, industry, and scientific communities regarding the use of plasma human immunodeficiency virus (HIV) ribonucleic acid (RNA) measurements in phase 3 clinical studies of antiretroviral drugs.

DATES: Written comments on the draft guidance may be submitted by November 30, 1999. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of the draft guidance for industry are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm''. Submit written requests for single copies of the draft guidance entitled ''Clinical Considerations for Accelerated and Traditional Approval of Antiretroviral Drugs Using Plasma HIV RNA Measurements'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments concerning the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5600 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jeffrey S. Murray, Center for Drug Evaluation and Research (HFD–530), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2495.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Clinical Considerations for Accelerated and Traditional Approval of Antiretroviral Drugs Using Plasma HIV RNA Measurements.'' The draft guidance summarizes the scientific basis supporting the use of HIV RNA as a primary study endpoint in both accelerated and traditional approvals of antiretroviral drugs. This summary is based on scientific data presented at a July 14 and 15, 1997, meeting of the Antiviral Drugs Advisory Committee. At this meeting, there was expert consensus that the use of plasma HIV RNA endpoints in certain situations could reliably predict clinical benefit. The draft guidance suggests that accelerated approvals could be based on studies that show a drug's contribution toward shorter-term reductions in HIV RNA (e.g., 24 weeks) while traditional approvals could be based on trials that show a drug's contribution toward durability of HIV RNA suppression (e.g., at least 48 weeks) in lieu of a traditional clinical endpoint study. Changes in CD4 cell counts should be consistent with observed HIV RNA changes when considering approval of an antiretroviral drug.

The draft guidance describes the agency's current thinking on clinical trial designs using HIV RNA changes as an endpoint for accelerated and traditional approvals. Considerations regarding control arms, study procedures, endpoints, and statistical methods for analyzing HIV RNA endpoints are discussed. The draft guidance also includes recommendations for sponsors who plan to use a new or unapproved HIV RNA assay in a clinical study. When using such assays, sponsors are encouraged to provide supporting data on the assay's limits and performance characteristics as outlined in the last section of the draft guidance.

This Level 1 draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on certain aspects of antiretroviral drug product