

Early Termination of the Waiting Period of the Premerger Notification Rules; Committee of Management of the National Coal Board Staff Superannuation Scheme

AGENCY: Federal Trade Commission.

ACTION: Granting of request for early termination of the waiting period of the premerger notification rules.

SUMMARY: Committee of Management of the National Coal Board Staff Superannuation Scheme is granted early termination of the waiting period provided by law and the premerger notification rules with respect to the proposed acquisition of all of the assets of Great Basins Petroleum Co. The grant was made by the Federal Trade Commission and the Assistant Attorney General in charge of the Antitrust Division of the Department of Justice in response to a request for early termination submitted by Committee of Management of the National Coal Board Superannuation Scheme. Neither agency intends to take any action with respect to this acquisition during the waiting period.

EFFECTIVE DATE: July 28, 1982.

FOR FURTHER INFORMATION CONTACT: Roberta Baruch, Senior Attorney, Premerger Notification Office, Bureau of Competition, Room 303, Federal Trade Commission, Washington, D.C. 20580 (202) 523-3894.

SUPPLEMENTARY INFORMATION: Section 7A of the Clayton Act, 15 U.S.C. 18a, as added by Title II of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, requires persons contemplating certain mergers or acquisitions to give the Commission and Assistant Attorney General advance notice and to wait designated periods before consummation of such plans. Section 7A(b)(2) of the Act permits the agencies, in individual cases, to terminate this waiting period prior to its expiration and requires that notice of this action be published in the Federal Register.

By direction of the Commission.
Carol M. Thomas,
Secretary.

[FR Doc. 82-22089 Filed 8-12-82; 8:45 am]

BILLING CODE 6750-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Consumer Participation; Open Meeting

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming national consumer exchange meeting to be chaired by the Commissioner of Food and Drugs.

DATE: The meeting will be held at 3:30 p.m., Monday, September 13, 1982.

ADDRESS: The meeting will be held in the Hubert H. Humphrey Bldg. Auditorium, 200 Independence Ave. SW., Washington, D.C. 20201. Interpreter services for deaf or hearing-impaired consumers will be provided upon request.

FOR FURTHER INFORMATION CONTACT: Alexander Grant, Associate Commissioner for Consumer Affairs (HFE-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5006; (TTY: telephone for the deaf) 301-443-1818.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to exchange information between FDA officials and consumer representatives, by providing an opportunity for consumer representatives to present their views directly to the Commissioner and to the top managers of FDA, by seeking solutions to any problems agreed on during this communication, and by giving the agency an opportunity to discuss and communicate vital health and policy issues to the concerned public. Proposed discussion at the meeting will focus on benefit-risk decisionmaking as it applies to recent drug issues and safety determinations as they apply to recent food issues.

Dated: August 4, 1982.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 82-21680 Filed 8-12-82; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 80P-0001]

RINN Corp.; Approval of Extension of Variance for "Condy Ray" Film Holder and X-ray Beam Alignment Instrument

Correction

In FR Doc. 82-20653 appearing on page 33008 of the issue of Friday, July 30, 1982 the Docket No. in the heading should have read as set forth above.

BILLING CODE 1505-01-M

[Docket No. 82G-0207]

Agriculture Canada, Research Branch; Filing of Petition for Affirmation of GRAS Status

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces that the Research Branch, Agriculture Canada, has filed a petition (GRASP 0G0266) proposing affirmation that the use of low erucic acid rapeseed oil as a food ingredient is generally recognized as safe (GRAS).

DATE: Comments by October 12, 1982.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vivian Prunier, Bureau of Foods (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-426-5487.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), and the regulations for affirmation of GRAS status under § 170.35 (21 CFR 170.35), notice is given that a petition (GRASP 0G0266) has been filed by Research Branch, Agriculture Canada, Ottawa, Ontario, Canada, K1A 0C5, and placed on public display at the Dockets Management Branch (address above), proposing affirmation that low erucic acid rapeseed oil is generally recognized as safe as a food ingredient.

Low erucic rapeseed oil (2 percent maximum erucic acid) is produced from low erucic acid-bearing rapeseed varieties derived from *Brassica napus* and *Brassica campestris*. Low erucic acid rapeseed oil and hydrogenated low erucic acid rapeseed oil are proposed for use as ingredients in food to the same extent as other edible fats and oils.

Interested persons may, on or before October 12, 1982 review the petition and/or file comments (two copies) identified with the docket number found in brackets in the heading of this document) with the Dockets Management Branch. Comments should include any available information that would be helpful in determining whether the substance is, or is not, GRAS. A copy of the petition and received comments may be seen in the Dockets Management Branch (address above), between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 3, 1982.

Sanford A. Miller,
Director, Bureau of Foods.

[FR Doc. 82-21850 Filed 8-12-82; 8:45 am]

BILLING CODE 4160-01-M

Consumer Participation; Notice of Open Meetings

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following consumer exchange meetings to be chaired by Hayward E. Mayfield, District Director, Nashville District Office.

DATES AND ADDRESSES: (1) Wednesday, August 25, 1982, 10 a.m. to 12 m., Conference Rm., Food and Drug Administration, 297 Plus Park Blvd., Nashville, TN 37217; (2) Friday, August 27, 1982, 11 a.m. to 12 m., 220 Bicentennial Blvd., Lawrenceburg, TN 38464.

FOR FURTHER INFORMATION CONTACT: Barbara B. Shields (August 25 meeting), Jessica A. Parchman (August 27 meeting), Consumer Affairs Officer, Food and Drug Administration, 297 Plus Park Blvd., Nashville, TN 37217, 615-251-7127.

SUPPLEMENTARY INFORMATION: The purpose of these meetings is to encourage dialogue between consumers and FDA officials, to identify and set priorities for current and future health concerns, to enhance understanding and exchange information between local consumers and FDA's District Offices, and to contribute to the agency's policymaking decisions on vital issues.

Dated: August 6, 1982.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-21849 Filed 8-12-82; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 82F-0229]

Goodyear Tire & Rubber Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Goodyear Tire & Rubber Co. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of styrenated diphenylamine as an antioxidant and/or stabilizer for polymers for food-contact use.

FOR FURTHER INFORMATION CONTACT: James H. Maryanski, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5740.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic

Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 2B3637) has been filed by Goodyear Tire & Rubber Co., Akron, OH 44316, proposing that § 178.2010

Antioxidants and/or stabilizers for polymers (21 CFR 178.2010) be amended to provide for the safe use of styrenated diphenylamine in § 175.105 *Adhesives* (21 CFR 175.105) and in § 177.2600 *Rubber articles intended for repeated use* (21 CFR 177.2600).

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.40(c) (proposed December 11, 1979; 44 FR 71742).

Dated: August 2, 1982.

Sanford A. Miller,
Director, Bureau of Foods.

[FR Doc. 82-21849 Filed 8-11-82; 8:45 am]

BILLING CODE 4160-01-M

Advisory Committee; Meeting

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also sets forth a summary of the procedures governing committee meetings and methods by which interested persons may participate in open public hearings conducted by the committees and is issued under section 10(a) (1) and (2) of the Federal Advisory Committee Act (Pub. L. 92-463, 86 Stat. 770-776 (5 U.S.C. App. I)), and FDA regulations (21 CFR Part 14) relating to advisory committees. The following advisory committee meeting is announced:

Ophthalmic Device Section of the Ophthalmic, Ear, Nose, and Throat; and Dental Devices Panel

Date, time, and place. September 20 and 21, 9 a.m., Rm. 1409, 200 C St. SW., Washington, DC.

Type of meeting and executive secretary. Open public hearing, September 20, 9 a.m., to 10 a.m.; open committee discussion, 10 a.m. to 1 p.m.; closed committee deliberations, 2 p.m. to 5 p.m.; open public hearing, September 21, 9 a.m. to 10 a.m.; open committee discussion, 10 a.m. to 1 p.m.; closed committee deliberations, 2 p.m. to 3 p.m.;

open committee discussion, 3 p.m. to 5 p.m.; George C. Murray, Bureau of Medical Devices (HFK-460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7940.

General function of the committee.

The committee reviews and evaluates available data on the safety and effectiveness of devices currently in use and makes recommendations for their regulation. The committee also reviews data on new devices and makes recommendations regarding their safety and effectiveness and their suitability for marketing.

Agenda—Open public hearing.

Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the executive secretary before September 7 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 required to make their comments.

Open committee discussion. On September 20, the committee will discuss premarket approval applications (PMA's) for intraocular lenses (IOL's) and may discuss PMA's for other ophthalmic products. If discussion of all pertinent IOL issues is not completed, discussion will be continued the following day. On September 21, the committee may discuss PMA's or general issues relating to contact lens or other ophthalmic products. The committee will also hold a final discussion on the revised draft contact lens guidelines and matrices for contact lens and contact lens products.

Closed committee deliberations. On September 20 and 21, the committee will conduct reviews of PMA's for IOL applications. On September 21, the committee may also discuss trade secret or confidential commercial information relevant to PMA's for contact lens products. These portions of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Each public advisory committee meeting listed above may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. The dates and times reserved

for the separate portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairman determines will facilitate the committee's work.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this Federal Register notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairman's discretion.

Persons interested in specific agenda items to be discussed in open session may ascertain from the contact person the approximate time of discussion.

A list of committee members and summary minutes of meetings may be requested from the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday. The FDA regulations relating to public advisory committees may be found in 21 CFR Part 14.

The Commissioner, with the concurrence of the Chief Counsel, has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA), as amended by the Government in the Sunshine Act (Pub. L. 94-409), permits such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a

clearly unwarranted invasion of personal privacy; investigatory files compiled for law enforcement purposes; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of date and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data of information that is not exempt from public disclosure pursuant to the FACA, as amended; and, notably deliberative sessions to formulate advice and recommendations to the agency on matters that do not independently justify closing.

Dated: August 6, 1982.

Arthur Hull Haynes, Jr.,
Commissioner of Food and Drugs.

[FR Doc. 21963 Filed 8-12-82; 8:45 am]

BILLING CODE 4160-01-M

International Multifoods; Napiana Broiler Concentrate Containing Roxarsone; Withdrawal of Approval of NADA

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new animal drug application (NADA) sponsored by

International Multifoods Corp. providing for use of Napiana Broiler Concentrate 3-nitro-4-hydroxyphenylarsonic acid (roxarsone) for growth stimulation in chickens and turkeys. The firm requested withdrawal of approval.

EFFECTIVE DATE: August 23, 1982.

FOR FURTHER INFORMATION CONTACT: Howard Meyers, Bureau of Veterinary Medicine (HFV-218), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4093.

SUPPLEMENTARY INFORMATION:

International Multifoods Corp., 1200 Multifoods Bldg., Eighth and Marquette Sts., Minneapolis, MN 55402, is the sponsor of NADA 9-028 which provides for use of Napiana Broiler Concentrate 3-nitro-4-hydroxyphenylarsonic acid (roxarsone), an intermediate premix containing 0.10 percent roxarsone which provides for growth stimulation in chickens and turkeys. The product, originally sponsored by Nappanee Milling Co., Nappanee, IN, became effective April 15, 1953. In their submission of March 11, 1982, to the Bureau of Veterinary Medicine, International Multifoods requested withdrawal of approval of the NADA because the product was no longer being marketed. Approval of this NADA had not been codified in the Code of Federal Regulations.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(e), 82 Stat. 345-347 (21 U.S.C. 360b(e))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.84) and in accordance with § 514.115 Withdrawal of approval of applications (21 CFR 514.115), notice is given that approval of NADA 9-028 and all supplements for Napiana Broiler Concentrate 3-nitro-4-hydroxyphenylarsonic acid (roxarsone) is hereby withdrawn, effective August 23, 1982.

Dated: August 6, 1982.

Lester M. Crawford,
Director, Bureau of Veterinary Medicine.

[FR Doc. 82-21964 Filed 8-12-82; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 82N-0266]

New Drug Status of OTC Combination Drug Products Containing Caffeine, Phenylpropanolamine, and Ephedrine

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces that it