

regular basis have the highest priority and are proposed for implementation as of December 1985. The simplification of the FR Y-6 would also be implemented for the December 1985 report. The remaining portions of the proposal—the new quarterly structure report and the new combined nonbank financial reports—would be implemented for reporting as of March 1986. Since this latter report constitutes a new reporting requirement, the later implementation date is intended to provide greater lead time to prospective filers and to avoid undue burden for the December reporting period.

Commenters are asked to address not only the general characteristics of the proposed reports, but also the specific items requested, the treatment of the items, and any reasonable alternatives for obtaining the information in a less burdensome fashion.

Other Issues

In addition, the Board requests comments on the treatment of the reports with respect to requests for confidentiality. Under existing procedures, all the information in the FR Y-6 and the FR Y-9 submitted to the Board is available to the public on request unless the bank holding company has requested confidential treatment and has demonstrated to the Board that disclosure of certain commercial or financial information would likely result in substantial harm to its competitive position or to the competitive position of its subsidiaries, or that disclosure of submitted information is of a personal nature that would result in a clearly unwarranted invasion of personal privacy. The Board has under consideration a proposal to make available to the public, upon request, all submissions of the FR Y-9 consolidated statements. The Board would propose to continue the current procedure with respect to the confidentiality of the parent company only and the nonbank financial statements.

The Board also seeks comments on a proposed new requirement to have three directors of the bank holding company attest to the correctness of the proposed reports as submitted to the Board. Currently, the reports require only the signature of a single official of the bank holding company. The Board believes that the proposed new requirement is consistent with the responsibilities of the directors to ensure that supervisory reports are accurate and is consistent with the responsibilities of the directors to be fully informed of the company's financial condition.

Regulatory Flexibility Act

The Board certifies that the proposed revision of the FR Y-6 reporting requirements is not expected to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The proposed revision of the FR Y-9 reporting requirements, including the FR 2352, will require small bank holding companies, those with assets of less than \$50 million, to provide certain parent company only information on a semiannual basis that was not previously required to be provided. The information that would be collected in the FR Y-9 is essential for the detection of emerging financial problems, the analysis of a bank holding company's financial condition and performance, the performance of pre-inspection analyses and the evaluation of bank holding company mergers and acquisitions. The imposition of these new standardized requirements is essential for the Board to supervise adequately the safety and soundness of small bank holding companies as required by the Bank Holding Company Act.

Board of Governors of the Federal Reserve System, July 3, 1985.

William W. Wiles,

Secretary of the Board.

[FR Doc. 85-16309 Filed 7-8-85; 8:45 am]

BILLING CODE 6210-01-M

GENERAL SERVICES ADMINISTRATION

Procedures for Ordering FY 1986 Updates to the Looseleaf Edition of the Federal Information Resources Management Regulation (FIRMR)

AGENCY: Office of Information Resources Management, GSA.

ACTION: Notice of procedures for Federal agencies/departments to order FY 1986 updates to the looseleaf edition of the FIRMR.

SUMMARY: This notice is to advise Federal agencies/departments to submit their FY 1986 copy requirements for the looseleaf edition of the FIRMR to the Government Printing Office (GPO). Individual agency offices are responsible for making their requirements known to their agency GPO Liaison Officers. Agency GPO Liaison Officers are responsible for submitting requirements to GPO through their Printing and Publishing Official. Agencies failing to submit orders will no longer receive FIRMR materials issued in FY 1986.

DATES: Applicable Dates: The looseleaf edition of the FIRMR was distributed to agencies by GPO in March of this year, based on agency-established copy requirements for FY 1985. Agencies must now submit their FY 1986 FIRMR copy requirements to GPO by August 15, 1985.

FOR FURTHER INFORMATION CONTACT: Carolyn A. Thomas, Policy Branch (KMPP), Office of Information Resources Management, telephone (202) 566-0194 or, FTS, 566-0194.

SUPPLEMENTARY INFORMATION: (1) The Federal Information Resources Management Regulation (FIRMR) established on April 1, 1984, is located in the Code of Federal Regulation at Title 41, Chapter 201. It provides Governmentwide regulations on the management, acquisition, and use of information resources (including automatic data processing, office automation, records management, and telecommunications).

(2) The basic looseleaf text of the FIRMR was distributed to agencies by the GPO in March of this year, based on agency-established copy requirements for FY 1985. GPO now requires agencies to submit their FY 1986 FIRMR copy requirements by August 15, 1985.

(3) Agency GPO Liaison Officers responsible for managing FIRMR distribution are being reminded to consolidate their agency's FY 1986 FIRMR copy requirements and make those requirements known to GPO through their agency Printing and Publication Official. In GPO Circular Number 201, dated April 25, 1985, GPO advised Federal Printing and Publication Officials to submit their agencies' FY 1986 copy requirements for all open requisitions (including the FIRMR) by June 21, 1985. However, GPO will continue to accept FY 1986 FIRMR copy requirements until August 15, 1985.

(4) FIRMR materials issued in FY 1986 will consist of updates to the basic looseleaf text only. The basic looseleaf text will not be reprinted for distribution in FY 1986. Federal employees unable to obtain the basic looseleaf text through their agency GPO Liaison Officer may subscribe to the FIRMR directly from GPO by following the procedures in paragraph six below.

(5) FIRMR updates in FY 1985 will continue to be issued under Transmittal Circulars (TC's) which will include amendments, temporary regulations, and bulletins and other informational guides. All FY 1986 production costs will be prorated to participating agencies by GPO. Based on estimated FY 1985 FIRMR costs of \$20.00 to \$25.00, FY 1986

costs are expected to be between \$10.00 and \$12.00 per user.

(b) Private sector companies, associations, businesses, and other interested parties wishing to receive the basic looseleaf text and all updates may place individual subscription orders directly with GPO by writing or calling, Superintendent of Documents, Government Printing Office, Washington, D.C. 20405, telephone: (202) 783-3238. The price for each subscription order is \$66.00 domestic and \$82.50 foreign. (GPO requires payment in advance unless charged to MasterCard, Visa, or GPO charge account.) Individuals already having a FIRM subscription directly with GPO will continue to receive FIRM updates in FY 1986 and are not required to reorder at this time.

Dated: June 28, 1985.

Larry L. Jackson,

Director, Policy and Regulations Division.

[FR Doc. 85-16325 Filed 7-8-85; 8:45 am]

BILLING CODE 6620-25-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 85F-0234]

Angus Chemical Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the Angus Chemical Co. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of 2-amino-2-methyl-1-propanol as a dispersing agent in pigment suspensions to be applied as coating to paper and paperboard products intended for food-contact use with aqueous foods.

FOR FURTHER INFORMATION CONTACT: Mary J. Stephens, Center for Food Safety and Applied Nutrition (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 5B3851) has been filed by the Angus Chemical Co., 2211 Sanders Rd., Northbrook, IL 60062, proposing that § 178.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 178.170) be amended to provide for the safe use of 2-amino-2-methyl-1-propanol as a dispersing agent

in pigment suspensions to be applied as coatings to paper and paperboard intended for food-contact use with aqueous foods.

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) (April 26, 1985; 50 FR 16636).

Dated: June 28 1985.

Sanford A. Miller,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 85-16208 Filed 7-8-85; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 85M-0290]

Bausch & Lomb Inc.; Premarket Approval of Bausch & Lomb * Sensitive Eyes™ Daily Cleaner

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Bausch & Lomb Inc., Rochester, NY, for premarket approval, under the Medical Device Amendments of 1976, of the Bausch & Lomb * Sensitive Eyes™ Daily Cleaner. After reviewing the recommendation of the Ophthalmic Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant of the approval of the application.

DATE: Petitions for administrative review by August 8, 1985.

ADDRESS: 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, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Richard E. Lippman, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7940.

SUPPLEMENTARY INFORMATION: On March 16, 1983, Bausch & Lomb Inc., Rochester, NY 14692, submitted to CDRH an application for premarket approval of the Bausch & Lomb * Sensitive Eyes™ Daily Cleaner. The device is indicated for use in cleaning soft (hydrophilic) contact lenses, in

conjunction with either thermal or chemical disinfection regimens. This cleaner may be used with extended wear soft (hydrophilic) contact lenses as often as daily or as recommended by the user's eye care practitioner. On November 18, 1983, the Ophthalmic Devices Panel, an FDA advisory committee, reviewed and recommended approval of the application. On June 5, 1985, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

Before enactment of the Medical Device Amendments of 1976 (the amendments) (Pub. L. 94-295, 90 Stat. 539-583), contact lenses made of polymethylmethacrylate (PMMA) and solutions for use with such contact lenses were regulated as new drugs. Because the amendments broadened the definition of the term "device" in section 201(h) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(h)), contact lenses made of polymers other than PMMA and solutions for use with such lenses are now regulated as class III devices (premarket approval). As FDA explained in a notice published in the *Federal Register* of December 16, 1977 (42 FR 63472), the amendments provide transitional provisions to ensure continuation of premarket approval requirements for class III devices formerly regulated as new drugs. Furthermore, FDA requires, as a condition to approval, that sponsors of applications for premarket approval of contact lenses made of polymers other than PMMA or solutions for use with such lenses comply with the records and reports provisions of Subpart D in Part 310 (21 CFR Part 310), until these provisions are replaced by similar requirements under the amendments.

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.

A copy of all approved labeling is available for public inspection at CDRH—contact Richard E. Lippman (HFZ-460), address above.

The labeling of the Bausch & Lomb * Sensitive Eyes™ Daily Cleaner states that the solution is indicated for use in the cleaning of soft (hydrophilic) contact lenses. Manufacturers of any soft (hydrophilic) contact lenses that have been approved for marketing are

advised that whenever CDRH publishes a notice in the *Federal Register* of CDRH's approval of a new solution for use with an approved soft contact lens, the manufacturer of each lens shall correct its labeling to refer to the new solution at the next printing or at any other time CDRH prescribes by letter to the manufacturer. A manufacturer who fails to update the restrictive labeling may violate the misbranding provisions of section 502 of the act (21 U.S.C. 352) as well as the Federal Trade Commission Act (15 U.S.C. 41-58), as amended by the Magnuson-Moss Warranty-Federal Trade Commission Improvement Act (Pub. L. 93-637). Furthermore, failure to update the restrictive labeling to refer to new solutions that may be used with an approved lens may be grounds for withdrawing approval of the application for the lens under section 515(e)(1)(F) of the act (21 U.S.C. 360e(e)(1)(F)).

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 (21 U.S.C. 360e(g)), 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 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 8, 1985, 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), 90 Stat. 554-555, 571 [21 U.S.C. 360e(d), 360(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: July 1, 1985.

John C. Villforth,

Director, Center for Devices and Radiological Health.

[FR Doc. 85-16209 Filed 7-8-85; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 85F-0233]

B.F. Goodrich Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the B.F. Goodrich Co. has filed a petition proposing to amend the food additive regulations to provide for the inclusion of a new use of 3,5-di-*tert*-butyl-4-hydroxyhydrocinnamic acid triester with 1,3,5-tris(2-hydroxyethyl)-s-triazine-2,4,6-(1*H*,3*H*,5*H*)-trione as a component of olefin and copolymers intended for use as food-contact articles.

FOR FURTHER INFORMATION CONTACT: Lester Borodinsky, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

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 5B3862) has been filed by B.F. Goodrich Co., Akron, OH 44318, proposing to amend the food additive regulations in 21 CFR 178.2010 to provide for the inclusion of a new use of 3,5-di-*tert*-butyl-4-hydroxyhydrocinnamic acid triester with 1,3,5-tris(2-hydroxyethyl)-s-triazine-2,4,6-(1*H*,3*H*,5*H*)-trione as a component of olefin copolymers intended for use as food-contact articles.

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) (April 26, 1985; 50 FR 16636).

Dated: June 29, 1985.

Sanford A. Miller,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 85-16207 Filed 7-8-85; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 85N-0263]

Neurotoxicity and Behavioral Dysfunction; Announcement of Symposium and Workshop; Request for Data and Information

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the Federation of American Societies for Experimental Biology (FAEB), Life Sciences Research Office (LSRO), will conduct a symposium and workshop to examine certain scientific issues related to neurotoxicity and behavioral dysfunction. The symposium will be open to the public. The workshop will be held by invitation only.

DATES: The symposium will be held on Monday, September 30, 1985, at the Bethesda Holiday Inn, 8120 Wisconsin Ave., Bethesda, MD, from 8:30 a.m. to 5 p.m. The workshop will be held on Tuesday October 1, 1985, at FASEB (address below). Relevant data and information may be submitted until September 23, 1985.

ADDRESSES: Relevant data and information should be submitted to both the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, and the Life Sciences Research Office, Federation of American Societies for Experimental Biology, 9650 Rockville Pike, Bethesda, MD 20814. Two copies of the relevant data and information should be submitted to both the FDA's Dockets Management Branch and the Life Sciences Research Office. Requests for information about the symposium and workshop should be made to the individuals listed below.

FOR FURTHER INFORMATION CONTACT:

Richard W. Leukroth, Jr., Life Sciences Research Office, Federation of American Societies for Experimental Biology, 9650 Rockville Pike, Bethesda, MD 20814, 301-530-7030;

or

Thomas J. Sobotka, Center For Food Safety and Applied Nutrition (HFF-162), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-245-1304.