

agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: December 9, 1996.

Douglas J. Godesky.

Reports Clearance Officer.

[FR Doc. 96-31702 Filed 12-12-96; 8:45 am]

BILLING CODE 4184-01-M

Food and Drug Administration

[Docket No. 96M-0461]

Allergan Optical; Premarket Approval of Refresh® CL Lubricating and Rewetting Drops

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Allergan Optical, Irvine, CA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of Refresh® CL Lubricating and Rewetting Drops. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of September 25, 1996, of the approval of the application.

DATES: Petitions for administrative review by January 13, 1997.

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: James F. Saviola, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1744.

SUPPLEMENTARY INFORMATION: On May 6, 1996, Allergan Optical, Irvine, CA 92713-9534, submitted to CDRH an application for premarket approval of Refresh® CL Lubricating and Rewetting Drops. The device is a solution indicated for the lubrication and rewetting of soft contact lenses. The device helps to relieve dryness, discomfort, and irritation that may be associated with lens wear.

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 Ophthalmic 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 September 25, 1996, CDRH approved the application by a letter to the applicant from the Director of the 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 (21 U.S.C. 360(g), 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 13, 1997, 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 24, 1996.

Joseph A. Levitt,

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

[FR Doc. 96-31744 Filed 12-12-96; 8:45 am]

BILLING CODE 4160-01-F

Investigational Biological Product Trials; Procedure to Monitor Clinical Hold Process; Meeting of Review Committee and Request for Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a meeting of its clinical hold review committee, which reviews the clinical hold orders that the Center for Biologics Evaluation and Research (CBER) has placed on certain investigational biological product trials. FDA is inviting any interested biological product company to use this confidential mechanism to submit to the committee for its review the name and number of any investigational biological product trial placed on clinical hold during the past 12 months that the company wants the committee to review.

DATES: The meeting will be held on February 11, 1997. Biological product companies may submit review requests for the February meeting by January 9, 1997.

ADDRESSES: Submit clinical hold review requests to Amanda Bryce Norton, FDA Chief Mediator and Ombudsman, Office of the Commissioner (HF-7), Food and Drug Administration, 5600 Fishers Lane, rm. 14-105, Rockville, MD 20857, 301-827-3390.

FOR FURTHER INFORMATION CONTACT: Joy A. Cavagnaro, Center for Biologics Evaluation and Research (HFM-2), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-0379.

SUPPLEMENTARY INFORMATION: FDA regulations in part 312 (21 CFR part 312) provide procedures that govern the use of investigational new drugs and biologics in human subjects. If FDA

determines that a proposed or ongoing study may pose significant risks for human subjects or is otherwise seriously deficient, as discussed in the investigational new drug regulations, it may order a clinical hold on the study. The clinical hold is one of FDA's primary mechanisms for protecting subjects who are involved in investigational new drug or biologic trials. Section 312.42 describes the grounds for ordering a clinical hold.

A clinical hold is an order that FDA issues to a sponsor to delay a proposed investigation or to suspend an ongoing investigation. The clinical hold may be ordered on one or more of the investigations covered by an investigational new drug application (IND). When a proposed study is placed on clinical hold, subjects may not be given the investigational drug or biologic as part of that study. When an ongoing study is placed on clinical hold, no new subjects may be recruited to the study and placed on the investigational drug or biologic, and patients already in the study should stop receiving therapy involving the investigational drug or biologic unless FDA specifically permits it.

When FDA concludes that there is a deficiency in a proposed or ongoing clinical trial that may be grounds for ordering a clinical hold, ordinarily FDA will attempt to resolve the matter through informal discussions with the sponsor. If that attempt is unsuccessful, a clinical hold may be ordered by or on behalf of the director of the division that is responsible for the review of the IND.

FDA regulations in § 312.48 provide dispute resolution mechanisms through which sponsors may request reconsideration of clinical hold orders. The regulations encourage the sponsor to attempt to resolve disputes directly with the review staff responsible for the review of the IND. If necessary, the sponsor may request a meeting with the review staff and management to discuss the clinical hold.

CBER began a process to evaluate the consistency and fairness of practices in ordering clinical holds by instituting a review committee to review clinical holds (see 61 FR 1033, January 11, 1996). CBER held its first clinical hold review committee meeting on May 17, 1995, and plans to conduct further quality assurance oversight of the IND process. The committee last met in November 1996. The review procedure of the committee is designed to afford an opportunity for a sponsor who does not wish to seek formal reconsideration of a pending clinical hold to have that clinical hold considered "anonymously." The committee

consists of senior managers of CBER, a senior official from the Center for Drug Evaluation and Research, and the FDA Chief Mediator and Ombudsman.

Clinical holds to be reviewed will be chosen randomly. In addition, the committee will review some of the clinical holds proposed for review by biological product sponsors. In general, a biological product sponsor should consider requesting review when it disagrees with FDA's scientific or procedural basis for the decision.

Requests for committee review of a clinical hold should be submitted to the FDA Chief Mediator and Ombudsman, who is responsible for selecting clinical holds for review. The committee and CBER staff, with the exception of the FDA Chief Mediator and Ombudsman, are never advised, either in the review process or thereafter, which of the clinical holds were randomly chosen and which were submitted by sponsors. The committee will evaluate the selected clinical holds for scientific content and consistency with FDA regulations and CBER policy.

The meetings of the review committee are closed to the public because committee discussions deal with confidential commercial information. Summaries of the committee deliberations, excluding confidential commercial information, may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. If the status of a clinical hold changes following the committee's review, the appropriate division will notify the sponsor.

FDA invites biological product companies to submit to the FDA Chief Mediator and Ombudsman the name and IND number of any investigational biological product trial that was placed on clinical hold during the past 12 months that they want the committee to review at its February 11, 1997, meeting. Submissions should be made by January 9, 1997, to Amanda Bryce Norton, FDA Chief Mediator and Ombudsman (address above).

Dated: December 9, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96-31745 Filed 12-12-96; 8:45 am]

BILLING CODE 4160-01-F

Health Resources and Services Administration

Rural Health Outreach and Rural Network Development Program

AGENCY: Health Resources and Services Administration (HRSA).

ACTION: Notice of availability of funds.

SUMMARY: The Office of Rural Health Policy announces that fiscal year 1997 funds are available for grants under the Rural Health Outreach, Network Development, and Telemedicine Grant Program. This announcement deals with the Rural Outreach and Rural Network Development aspects of the program. The Telemedicine grants will be announced separately.

Two kinds of projects will be funded under this announcement: (1) Rural Outreach Grants for the development of innovative new service delivery systems in rural areas where support is provided for the actual delivery of new services or enhancement of existing services, and (2) Rural Network Development Grants for the planning and development of vertically integrated networks in rural areas where the emphasis is placed not on the actual delivery of services, but on efforts to restructure the delivery system in rural communities. Funds were appropriated for these grants under Public Law 104-208. The grants are authorized by Section 330A of the Public Health Service Act as amended by the Health Centers Consolidation Act of 1996, Public Law 104-299.

Applicants may not apply for both the Rural Outreach Grants and the Rural Network Development Grants.

NATIONAL HEALTH OBJECTIVES FOR THE YEAR 2000: The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity for setting priority areas. The Rural Health Outreach, Network Development, and Telemedicine Grant Program is related to the priority areas for health promotion, health protection and preventive services. Potential applicants may obtain a copy of Healthy People 2000 (Full Report: Stock No. 017-001-00474-C) Or Healthy People (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402-9325 (Telephone (202)783-3238).

FUNDS AVAILABLE: Appropriations for FY 1997 include \$16 million to support Rural Outreach and Rural Network Development Grants. Of this amount, it is anticipated that about \$8 million will be available to support 40 new Rural