SUMMARY: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. No. 92–463), as amended, notice is hereby given that a public hearing of the Federal Accounting Standards Advisory Board will be held on Thursday, December 18, 1997 from 1:00 P.M. to 4:00 P.M. in room 7C13 of the General Accounting Office, 441 G St., N.W., Washington, D.C.

The purpose of the hearing is to hear testimony from interested parties on Accounting for Internal Use Software. Those interested in testifying should contact Wendy Comes, Executive Director, no later than one week prior to the hearing. Also, they should at the same time provide a short biography and written copies of their testimony.

Any interested person may attend the hearing as an observer. Board discussions and reviews are open to the public.

FOR FURTHER INFORMATION CONTACT: Wendy M. Comes, Executive Staff Director, 441 G St., N.W., Room 3B18, Washington, D.C. 20548, or call (202) 512–7357. E-Mail to: ComesW.fasab@gao.gov. Fax: 202–512–7366.

Authority: Federal Advisory Committee Act. Pub. L. No. 92–463, Section 10(a)(2), 86 Stat. 770, 774 (1972) (current version at 5 U.S.C. app. section 10(a)(2) (1988); 41 CFR 101–6.1015 (1990).

Dated: December 3, 1997.

Wendy M. Comes,

Executive Director.

[FR Doc. 97–32191 Filed 12–8–97; 8:45 am]

BILLING CODE 1610–01–M

GENERAL ACCOUNTING OFFICE

Federal Accounting Standards Advisory Board

AGENCY: General Accounting Office.

ACTION: Notice of December meeting.

SUMMARY: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. No. 92–463), as amended, notice is hereby given that the Federal Accounting Standards Advisory Board will meet on Friday, December 19, 1997, from 9 a.m. to 4 p.m. in Room 7C13 of the General Accounting Office building, 441 G St., NW., Washington, DC.

The purpose of the meeting is to discuss the following issues: (1) Natural Resources; (2) Credit Reform proposed amendments; (3) Social Insurance; (4) follow-up issues from the public hearing on accounting for internal use software of December 18; and (5) the addition of new projects for 1998.

Any interested person may attend the meeting as an observer. Board discussions and reviews are open to the public.

FOR FURTHER INFORMATION CONTACT: Wendy Comes, Executive Director, 441 G St., NW., Room 3B18, Washington, DC 20548, or call (202) 512–7350.

Authority: Federal Advisory Committee Act, Pub. L. No. 92–463, Section 10(a)(2), 86 Stat. 770, 774 (1972) (current version at 5 U.S.C. app. section 10(a)(2) (1988); 41 CFR 101–6.1015 (1990).

Dated: December 3, 1997.

Wendy M. Comes,

Executive Director.

[FR Doc. 97–32192 Filed 12–8–97; 8:45 am]

BILLING CODE 1610–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N-0496]

Agency Emergency Processing Request Under OMB Review

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The purpose of the proposed collection of information is to enable FDA to comply in a timely manner with the congressional mandate in section 504 of the Federal Food Drug and Cosmetic Act (the act) as added by the Animal Drug Availability Act (ADAA) of 1996, which requires that distributors of animal feeds containing a veterinary feed directive (VFD) drug notify FDA of their intent to engage in distribution. FDA is requesting OMB approval within 10 days of receipt of this clearance submission.

DATES: Submit written comments by December 19, 1997.

ADDRESSES: Submit written comments to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

SUPPLEMENTARY INFORMATION: FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA and 5 CFR 1320.13 because the information is needed so that FDA can process letters from animal feed distributors notifying the agency of their intent to distribute animal feeds containing VFD drugs as mandated by the ADAA.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Newley added section 504 of the act (21 U.S.C. 354) created a new class of drugs for use in animal feed, referred to as VFD drugs, which are limited to use only under the professional supervision of a licensed veterinarian. Under section 504(a)(3)(C) (21 U.S.C. 354(a)(3)(C)), a distributor must upon first engaging in the distribution of animal feeds containing VFD drugs notify the agency of its name and place of business. The information the agency needs to implement this statutory requirement includes the following specific information: Distributor name, site street address, mailing address (if different), city state, zip code, name and title of individual submitting the letter, the date signed, and a statement acknowledging the intent to distribute. The information will be used as confirmation of distributors for this new class of drugs. To date, FDA has received letters from approximately 500 distributors. FDA is working diligently to implement procedural regulations for VFD drugs. Thus, approval of this request by OMB will allow FDA to obtain the information that distributors must provide under section 504(a)(3)(C) as well as provide the agency with a listing of distributors legally authorized to distribute animal feeds containing VFD drugs.

Respondents to this collection of information are animal feed and animal drug distributors. FDA estimates the

burden of the proposed collection of information is as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
354(a)(3)(C)	20,000	1	1 (initial only)	.25	5,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimate for this proposed burden was derived from agency records and past experience concerning animal feed distribution.

Dated: December 3, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–32163 Filed 12–8–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M–0499]

ALLERGAN Medical Optics; Premarket Approval of Model SA40N AMO®ARRAY® Multifocal Ultraviolet-Absorbing Silicone Posterior Chamber Intraocular Lens

AGENCY: Food and Drug Administration, HHS

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Allergan Medical Optics, Irvine, CA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of Model SA40N AMO®Array® Multifocal Ultraviolet-Absorbing Silicone Posterior Chamber Intraocular Lens. After reviewing the recommendation of the Ophthalmic Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of September 5, 1997, of the approval of the application.

DATES: Petitions for administrative review by January 8, 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: Ashley A. Boulware, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2053.

SUPPLEMENTARY INFORMATION: On September 3, 1996, Allergan Medical Optics, Irvine, CA 92612–9534, submitted to CDRH an application for premarket approval of Model SA40N AMO®Array® Multifocal Ultraviolet-Absorbing Silicone Posterior Chamber Intraocular Lens. The device is a multifocal intraocular lens and is indicated for the visual correction of aphakia in persons 60 years of age or older in whom a cataractous lens has been removed and who may benefit from useful near vision without reading add and increased spectacle independence across a range of distances where the potential visual effects associated with multifocality are acceptable. The lens is intended for placement in the capsular bag. The lens is available in powers of +16 to +24 diopters.

On July 10, 1997, the Ophthalmic Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On September 5, 1997, 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 (21 U.S.C. 360e(d)(3)) 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 8, 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. 97–32165 Filed 12–8–97; 8:45 am]

BILLING CODE 4160–01–F