

which summaries of safety and effectiveness were placed on the Internet from October 1, 2002, through

December 31, 2002. There were no denial actions during this period. The list provides the manufacturer's name,

the product's generic name or the trade name, and the approval date.

TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE OCTOBER 1, 2002, THROUGH DECEMBER 31, 2002.

PMA Number/Docket No.	Applicant	Trade Name	Approval Date
P010043/02M—0471 P970043(S10)/02M—0487 P020004/02M—0527	Yama, Inc. Alcon Laboratories, Inc. W.L. Gore & Associates, Inc.	LEA'S SHIELD Barrier Contraceptive LADARVISION 4000 Excimer Laser System EXCLUDER Bifurcated Endoprosthesis	March 14, 2002. October 18, 2002. November 6, 2002.

II. Electronic Access

Persons with access to the Internet may obtain the documents at <http://www.fda.gov/cdrh/pmapage.html>.

Dated: March 13, 2003.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 03-7279 Filed 3-25-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Circulatory System 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). The meeting will be open to the public.

Name of Committee: Circulatory System 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 April 10, 2003, from 9 a.m. to 5 p.m.

Location: Hilton DC North/Gaithersburg, Salons A, B, and C, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Geretta Wood, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8320, ext. 143, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12625. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application for an endovascular graft and delivery system intended for the treatment of patients with abdominal aortic, aortoiliac, or iliac aneurysm. Background information for the topic, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting on the Internet at <http://www.fda.gov/cdrh/panelmtg.html>. Material will be posted on April 9, 2003.

Procedure: 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 April 3, 2003. Oral presentations from the public will be scheduled for approximately 30 minutes at the beginning of committee deliberations and for approximately 30 minutes near the end of the deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 3, 2003, 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.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Shirley Meeks, Conference Management Staff, at 301-594-1283, ext. 105, at least 7 days in advance of the meeting.

FDA regrets that it was unable to publish this notice 15 days prior to the April 10, 2003, Circulatory System Devices Panel of the Medical Devices

Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Circulatory System Devices Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 20, 2003.

Linda Arey Skladany,

Associate Commissioner for External Relations.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Maternal and Child Health Services Title V Block Grant Program—Guidance and Forms for the Title V Application/Annual Report (OMB No. 0915-0172)—Revision

The Health Resources and Services Administration (HRSA) proposes to revise the *Maternal and Child Health Services Title V Block Grant Program—Guidance and Forms for the Application/Annual Report*. The guidance is used annually by the 50 States and 9 jurisdictions in making application for Block Grants under Title V of the Social Security Act, and in preparing the required annual report.

The proposed revisions follow and build on extensive consultation received from a Workgroup convened in 2002 to provide suggestions for improving the guidance and forms. The proposed revisions are editorial and technical revisions in nature, and are based on the experience of the States and jurisdictions using previous versions of the guidance. Changes include consolidating the narrative to reduce redundancy, and reducing the number of Health Status Indicators (HSI) required in the application/annual report.

In addition, HRSA proposes changing the format for electronic submission to

direct web entry. Web based data and text entry will provide for automatic calculation of ratios, rates, and percentages, carry data over year-to-year, and assure that data used in multiple tables are entered only once. It will also facilitate the orderly printing of tables, text, and required appendices.

The guidance used annually by the 50 States and 9 jurisdictions had a previous estimated burden of 358 hours. Based on the new revisions and more efficient electronic submission, the estimated burden has been reduced by 5% to 322 hours. The estimated response burden is as follows:

Type of form	Number of respondents	Responses per respondent	Burden hours per response	Total burden hours
Application and Annual Report, with needs assessment*:				
States	50	1	428	21,400
Jurisdictions	9	1	228	2,052
Application and Annual Report, without needs assessment*:				
States	50	1	313	15,658
Jurisdictions	9	1	126	1,134

* The Application and Annual Report, with needs assessment, will be submitted in FY 2005. The Application and Annual Report, without needs assessment, will be submitted in FY 2003 and FY 2004. The average annual total burden hours for the next three years is 19,007. The average annual burden per respondent 322 hours.

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: John Morrall, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: March 19, 2003.

Jane M. Harrison,
Director, Division of Policy Review and Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Agency Information Collection Activities: Proposed Collection and Comment Request (OIG-319-N)

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of Inspector General (OIG) is publishing for public comment the following summary of proposed collection activities. Interested parties

are invited to send comments to the address indicated below regarding this burden estimate or any other aspect of this collection of information, including (1) the necessity and utility of proposed information collection for the proper performance of the OIG's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

SUPPLEMENTARY INFORMATION:

Type of Information Collection
Request: Reinstatement of an expired collection.

Title of Information Collection: State Medicaid Fraud Control Units' Recertification Application and Annual Report as required by 42 CFR 1007.15 and 1007.17. (Previously approved by the Office of Management and Budget under control number 0990-0162.)

Use: The information contained in the annual reports and recertification application is required for certification and yearly recertification by the OIG to ensure that federal matching funds are only expended for allowable costs, and to determine if a state unit needs financial assistance.

Frequency: Annually.
Affected Public: State government.
Annual Number of Respondents: 48.
Total Annual Responses: 48.

Average Burden Per Response: 32 hours.

Total Annual Hours: 2,744 hours.

FOR FURTHER INFORMATION CONTACT: To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address and phone number, to John Bettac, Office of Investigations (Jbettac@oig.hhs.gov), or call (202) 619-3557.

DATE: To assure consideration, public comments must be delivered to address provided below by no later than 5 p.m. on May 27, 2003.

ADDRESSES: Written comments and recommendations for proposed information collections should be mailed or delivered to the following address: Office of Inspector General, Department of Health and Human Services, Attention: John Bettac, Room 5453, Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201.

We do not accept comments by facsimile (FAX) transmission. In commenting, please refer to file code OIG-319-N. Comments received timely will be available for public inspection as they are received beginning approximately 3 weeks after publication of a document in Room 5541 of the Office of Inspector General at 330 Independence Avenue, SW.,