

Dated: January 22, 1998.

Laura M. Tarantino,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 98-3205 Filed 2-6-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98M-0050]

American Medical Systems Inc.; Premarket Approval of the UroLume™ Endourethral Prostatic for Prostatic Obstruction Secondary to Benign Prostatic Hypertrophy

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by American Medical Systems Inc., Minnetonka, MN, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the UroLume™ Endourethral Prostatic for Prostatic Obstruction Secondary to Benign Prostatic Hypertrophy (BPH). After reviewing the recommendation of the Gastroenterology-Urology Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of April 11, 1997, of the approval of the application.

DATES: Petitions for administrative review by March 11, 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: James P. Seiler, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2194.

SUPPLEMENTARY INFORMATION: On May 6, 1996, American Medical Systems Inc., Minnetonka, MN 55343, submitted to CDRH an application for premarket approval of the UroLume™ Endourethral Prostatic for Prostatic Obstruction Secondary to BPH. The device is intended to relieve prostatic obstruction secondary to BPH in men at least 60 years of age, or men under 60 years of age who are poor surgical

candidates, and whose prostates are at least 2.5 centimeters in length.

On January 16, 1997, the Gastroenterology-Urology Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On April 11, 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 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 March 11, 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 17, 1997.

Joseph A. Levitt,

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

[FR Doc. 98-3206 Filed 2-6-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Final Special Factors for Grants for Residency Training and Advanced Education in the General Practice of Dentistry Programs for Fiscal Year 1998

Grants for Residency Training and Advanced Education in the General Practice of Dentistry Programs are authorized under section 749, Title VII of the Public Health Service Act, as amended by the Health Professions Education Extension Amendments of 1992, Public Law 102-408, dated October 13, 1992.

Final Special Factors

In determining the funding of approved applications, the Secretary will consider the following Special Factors:

Community linkages-this special factor may be addressed by the establishment of academic-community linkages, in particular linkages between the training program and underserved populations or communities. Documentation of such linkages should include verification that at least 20% of residents' training time occurs in one or more underserved settings. Memoranda of agreement and letters of support from the community settings involved should be included in the appropriate appendix of the application.

Establishment of new PGY-1 training positions-to address the recommendations of expert panels such as the Institute of Medicine and Pew Commission on Health that a year of post-doctoral training be available for all dental graduates, and that the majority of these positions be in general dentistry programs. This special factor may be addressed by the establishment of new postgraduate year-one (PGY-1) training positions, either through the establishment of a new program or the expansion of an existing program. An

increase in the number of PGY-2 positions does not address the intent of this special factor.

Innovative training methods-examples of ways in which applicants address this special factor might include new sponsor/co-sponsor arrangements; different organizational and administrative structures; expanded private/public sector affiliations and setting linkages; and creative applications for current instructional telecommunications and computer technologies.

Peer reviewers will take into consideration the extent to which proposals address these Special Factors and adjust their individual technical review scores accordingly.

A notice was published in the **Federal Register** at 62 FR 62616 on November 24, 1997, for the proposed special factors for the above-referenced program. No comments were received within the 30 day comment period. Therefore, the special factors remain as proposed.

If additional information is needed, please contact: Bernice Parlak, Division of Associated, Dental and Public Health Professions, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Room 8-101, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone: (301) 443-6853, FAX: (301) 443-1164.

Dated: January 30, 1998.

Claude Earl Fox,

Acting Administrator.

[FR Doc. 98-3090 Filed 2-5-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

"Low Income Levels" for Health Professions and Nursing Programs

The Health Resources and Services Administration (HRSA) is updating income levels used to identify a "low income family" for the purpose of providing training for individuals from disadvantaged backgrounds under various health professions and nursing programs included in Titles VII and VIII of the Public Health Service Act (the Act).

The Department periodically publishes in the **Federal Register** low income levels used for grants and cooperative agreements to institutions providing training for individuals from disadvantaged backgrounds. A "low

income level" is one of the factors taken into consideration to determine if an individual qualifies as a disadvantaged student for purposes of health professions and nursing programs.

The programs under the Act that use "low income levels" as one of the factors in determining disadvantaged backgrounds include the Health Careers Opportunity Program, section 740, the Program of Financial Assistance for Disadvantaged Health Professions Students, section 740 (a)(2)(F), and Nursing Education Opportunities for Individuals from Disadvantaged Backgrounds, section 827. Loans to Disadvantaged Students, section 724, Scholarships for Health Professions Students from Disadvantaged Backgrounds, section 737, Disadvantaged Health Professions Faculty Loan Repayment and Fellowships Program, section 738 were added to Title VII by the Disadvantaged Minority Health Improvement Act of 1990 (Pub. L. 101-527) and are also using the low income levels. Other factors used in determining "disadvantaged backgrounds" are included in individual program regulations and guidelines.

Health Careers Opportunity Program (HCOP), Section 740

This program awards grants to accredited schools of medicine, osteopathic medicine, public health, dentistry, veterinary medicine, optometry, pharmacy, allied health, podiatric medicine, chiropractic and public or nonprofit private schools which offer graduate programs in clinical psychology, and other public or private nonprofit health or educational entities to assist individuals from disadvantaged backgrounds to enter and graduate from health professions schools.

Financial Assistance for Disadvantaged Health Professions Students (FADHPS), Section 740 (a)(2)(F)

This program awards grants to accredited schools of medicine, osteopathic medicine, and dentistry to provide financial assistance to individuals from disadvantaged backgrounds who are of exceptional financial need to help pay for their health professions education. The provision of these scholarships shall be subject to section 795 relating to residency training and practice in primary health care.

Nursing Education Opportunities for Individuals From Disadvantaged Backgrounds, Section 827

This program awards grants to public and nonprofit private schools of nursing and other public or nonprofit private entities to meet costs of special projects to increase nursing education opportunities for individuals from disadvantaged backgrounds.

Loans to Disadvantaged Students, Section 724

This program makes awards to certain accredited schools of medicine, osteopathic medicine, dentistry, pharmacy, optometry, podiatric medicine, and veterinary medicine for financially needy students from disadvantaged backgrounds.

Scholarships for Health Professions Students From Disadvantaged Backgrounds, Section 737

This program awards grants to schools of medicine, nursing, osteopathic medicine, dentistry, pharmacy, podiatric medicine, optometry, veterinary medicine, allied health, or public health, or schools that offer graduate programs in clinical psychology for the purpose of assisting such schools in providing scholarships to individuals from disadvantaged backgrounds who enrolled (or are accepted for enrollment) as full-time students.

Disadvantaged Health Professions Faculty Loan Repayment and Fellowship Program, Section 738

This program awards grants to repay the health professions education loans of disadvantaged health professionals who have agreed to serve for at least 2 years as a faculty member of a school of medicine, nursing, osteopathic medicine, dentistry, pharmacy, podiatric medicine, optometry, veterinary medicine, public health, or a school that offers a graduate program in clinical psychology. Section 738 (a) allows loan repayment only for an individual who has not been a member of the faculty of any school at any time during the 18-month period preceding the date on which the Secretary receives the request of the individual for repayment contract (ie., "new" faculty).

The following income figures were taken from low income levels published by the U.S. Bureau of the Census, using an index adopted by a Federal Interagency Committee for use in a variety of Federal programs. That index includes multiplication by a factor of 1.3 for adaptation to health professions and nursing programs which support training for individuals from