

(sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 8B4567) has been filed by General Electric Co., One Lexan Lane, Mt. Vernon, IN 47620-9364. The petition proposes to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to provide for the expanded safe use of phosphorous acid, cyclic butylethyl propanediol, 2,4,6-tri-tert-butylphenyl ester, which may contain up to 1 percent by weight of triisopropanolamine, as an antioxidant and/or stabilizer in high density polyethylene and high density olefin copolymers intended for use in contact with food.

The agency has determined under 21 CFR 25.32(i) that this action is of the type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: November 3, 1997.

Alan M. Rulis,

*Director, Office of Premarket Approval,
Center for Food Safety and Applied Nutrition.*
[FR Doc. 97-30484 Filed 11-19-97; 8:45 am]

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**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

Food and Drug Administration

[Docket No. 97M-0457]

**Urologix, Inc.; Premarket Approval of
the T3® Targeted Transurethral
Thermoablation System: Model 4000**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Urologix, Inc., Minneapolis, MN, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the T3® Targeted Transurethral Thermoablation System: Model 4000. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of August 22, 1997, of the approval of the application.

DATES: Petitions for administrative review by December 22, 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: Nicole L. Wolanski, Center for Devices and Radiological Health (HFZ-472), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2194.

SUPPLEMENTARY INFORMATION: On February 24, 1997, Urologix, Inc., Minneapolis, MN 55447, submitted to CDRH an application for premarket approval of the T3® Targeted Transurethral Thermoablation System: Model 4000. The device is a transurethral microwave thermal therapy system and is indicated to relieve symptoms associated with benign prostatic hyperplasia (BPH) and is indicated for men with prostatic lengths of 30 to 50 millimeters.

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 Gastroenterology and Urology 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 August 22, 1997, CDRH approved the application by a letter to the applicant from the Deputy Director, Clinical and Review Policy, 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, 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 December 22, 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 16, 1997.

Joseph A. Levitt,

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

[FR Doc. 97-30482 Filed 11-19-97; 8:45 am]

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**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

Health Care Financing Administration

[Document Identifier: HCFA-R-219]

**Agency Information Collection
Activities: Proposed Collection;
Comment Request**

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) the necessity and utility of the proposed information collection for the proper

performance of the agency'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.

Type of Information Collection Request: New Collection; *Title of Information Collection:* End Stage Renal Disease (ESRD) Managed Care Demonstration Evaluation; *Form No.:* HCFA-R-219; *Use:* This demonstration is congressionally mandated under the Social Health Maintenance Organization (SHMO) requirements. This evaluation will demonstrate the effectiveness of integrating acute and chronic care patients with ESRD through expanded community care case management services, using innovative approaches to financing methodologies and benefit design. *Frequency:* Other 0, 12, and 30 months; *Affected Public:* Business or other for-profit, Individuals or Households; *Number of Respondents:* 5,365; *Total Annual Responses:* 5,365; *Total Annual Hours:* 4,431.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, or to obtain the supporting statement and any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address:

HCFA, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Attention: John Rudolph, Room C2-26-17, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: November 12, 1997.

John P. Burke III,

HCFA Reports Clearance Officer, Division of HCFA Enterprise Standards, Health Care Financing Administration.

[FR Doc. 97-30471 Filed 11-19-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-64]

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) the necessity and utility of the proposed information collection for the proper performance of the agency'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.

Type of Information Collection Request: Reinstatement, without change, of a previously approved collection for which approval has expired; *Title of Information Collection:* Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program; *Form No.:* HCFA-64; *Use:* This form is used by State Medicaid agencies to report their actual program benefit costs and administrative expenses to the Health Care Financing Administration (HCFA). HCFA uses this information to compute the Federal financial participation (FFP) for the State's Medicaid Program costs. *Frequency:* Quarterly; *Affected Public:* State, Local or Tribal Government; *Number of Respondents:* 56; *Total Annual Responses:* 224; *Total Annual Hours:* 11,984.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, or to obtain the supporting statement and any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services,

Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Attention: John Rudolph, Room C2-26-17, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: November 14, 1997.

John P. Burke III,

HCFA Reports Clearance Officer, Division of HCFA Enterprise Standards, Health Care Financing Administration.

[FR Doc. 97-30530 Filed 11-19-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-316]

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) the necessity and utility of the proposed information collection for the proper performance of the agency'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.

Type of Information Collection Request: Reinstatement without change of a previously approved collection for which approval has expired; *Title of Information Collection:* Medicaid, Integrated Quality Control Review Worksheet and Supporting Regulations 42 CFR 431.800, 42 CFR 431.865; *Form No.:* HCFA-316 OMB # 0938-0094; *Use:* States use the Integrated Quality Control Review Worksheet to collect quality control (QC) data captured during the course of all Federally required State QC reviews of Food Stamp (FS) and Medicaid programs. The integrated worksheet is designed to be flexible for use in fully integrated, partially integrated, or separate QC program reviews. The primary objective of the QC system is to measure, identify, and