

(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.*

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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