of each person engaged in the manufacturing, processing, packing, or holding of a drug product to have the necessary education, training, and experience to perform their assigned functions § 211.25(a) (21 CFR 211.25(a)); (2) failure to thoroughly investigate any unexplained discrepancy in drug product production and control records or the failure of a batch to meet any of its specifications (21 CFR 211.192); (3) failure to establish separate or defined areas or other control systems for manufacturing and processing operations to prevent contamination or mixups (§ 211.42(c) (21 CFR 211.42(c)) and 21 CFR 600.11(a)); (4) failure to establish and follow appropriate written procedures designed to prevent microbiological contamination of drug products purporting to be sterile and to assure that such procedures include validation of any sterilization processes (21 CFR 211.113(b)); (5) failure to report adverse experience information (21 CFR 600.80(c)); (6) failure to establish laboratory controls that include scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity (21 CFR 211.160(b)); (7) failure to provide adequate space for the orderly placement of equipment and materials to prevent mixups between different components, drug product containers, closures, labeling, in-process materials, or drug products, and to prevent contamination (§ 211.42(b)); (8) failures to establish and/or follow written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess and to assure that such procedures, including any changes, are drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by quality control (21 CFR 211.100); (9) failure to maintain buildings used in the manufacture, processing, packing, or holding of a drug product in a good state of repair (21 CFR 211.58); and (10) failure to demonstrate that adequate ventilation is provided (21 CFR 211.46(a)).

Based on the results of FDA's inspection and investigation, FDA determined that the firm's Coccidioidin, USP (BioCox) was adulterated within the meaning of section 501(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 351(b)) and in violation of section 351(a) of the Public Health Service Act (the PHS Act) (42 U.S.C. 262(a)). These products were also misbranded within the meaning of section 502(a) of the act (21 U.S.C. 352(a)).

FDA concluded that the nature of the deficiencies noted at Iatric Corp. were the direct consequence of a disregard for the applicable regulations and standards in the license application. These deficiencies also demonstrated management's failure to exercise control over the establishment in all matters relating to compliance and to ensure that personnel are adequately trained and supervised and have a thorough understanding of the procedures that they perform, as required by § 211.25. FDA determined that these deficiencies constitute a danger to the public health that warranted suspension under § 601.5(b) (21 CFR 601.5(b)) and 21 CFR 601.6(a).

In a letter to the firm dated April 25, 1997, FDA suspended the establishment license (U.S. License No. 0416) and product license for Coccidioidin, USP (BioCox). In a letter dated May 13, 1997, Iatric Corp. requested voluntary revocation of its product license for the manufacture of Coccidioidin, USP (BioCox).

FDA has placed copies of the letters relevant to the license revocation on file under the docket number found in brackets in the heading of this document with the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. These documents are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Accordingly, under § 601.5(a), section 351 of the PHS Act, and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Biologics Evaluation and Research (21 CFR 5.68), the product license issued to Iatric Corp. for the manufacture of Coccidioidin, USP (BioCox) was revoked, effective June 25, 1997.

This notice is issued and published under 21 CFR 601.8 and the redelegation at 21 CFR 5.67(c).

Dated: October 31, 1997.

Mark Elengold,

Acting Deputy Director, Center for Biologics Evaluation and Research.

[FR Doc. 97–30028 Filed 11–13–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M–0453]

HealthTronics, Inc.; Premarket Approval of Lithotron™ Lithotripsy System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application submitted by HealthTronics, Inc., Marietta, GA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the LithoTron™ Lithotripsy System. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of July 21, 1997, of the approval of the application.

DATES: Petitions for administrative review by December 15, 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: Russell P. Pagano, 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 16, 1997, HealthTronic, Inc., Marietta, GA 30060, submitted to CDRH an application for premarket approval of the LithoTron™ Lithotripsy System. The device is an extracorporeal shockwave lithotripter and is indicated for use in patients with renal and upper ureteral calculi between 4 and 20 millimeters in size.

In accordance with the provisions of section 515(c)(2) of the the act (21 U.S.C. 360e(c)(2)) as amended by the Safe Medical Devices Act of 1990, this premarket approval 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 July 21, 1997, CDRH approved the application by a letter to the applicant from the Deputy Director of Clinical and

Review Policy 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 December 15, 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 17, 1997.

Joseph A. Levitt,

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

[FR Doc. 97–30029 Filed 11–13–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M–0458]

NeuroControl, Corp.; Premarket Approval of Freehand System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application submitted by NeuroControl, Corp., Cleveland, OH, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the Freehand System . After reviewing the recommendation of the Neurological Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of August 15, 1997, of the approval of the application.

DATES: Petitions for administrative review by December 15, 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: Levering G. Keely, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8517.

SUPPLEMENTARY INFORMATION: On June 17, 1996, NeuroControl Corp., Cleveland, OH 44106, submitted to CDRH an application for premarket approval of the Freehand System . The system includes: Implantable receiver-stimulator Model 202–1, implantable epimysial electrode set Model 203–1, surgical electrode positioning kit Model 207–1, patient external system Model 204–1, and programming system Model 209–1. The system is an upper extremity neuroprosthesis and is intended to improve a patient's ability to grasp, hold, and release objects. The system is indicated for use in patients who: (1) Are tetraplegic due to C5 or C6 spinal cord injury (ASIA Classification), (2) have adequate functional range of motion of the upper extremity, (3) have intact lower motor neuron innervation of the forearm and hand musculature, and (4) are skeletally mature.

On September 25, 1996, the Neurological Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On August 15, 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 December 15, 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.