GENERAL ACCOUNTING OFFICE

Advisory Council on Government Auditing Standards; Notice of Meeting

The Advisory Council on Government Auditing Standards will meet on Monday, November 24, 1997, from 9:00 a.m. to 5:00 p.m., and Tuesday, November 25, 1997, from 8:30 a.m. to 3:00 p.m., in room 7C13 of the General Accounting Office building, 441 G St., NW., Washington, D.C.

The Advisory Council on Government Auditing Standards will hold a meeting to discuss issues that may impact Government Auditing Standards. Any interested person may attend the meeting as an observer. Council discussions and reviews are open to the public.

For further information contact: Marcia Buchanan, Assistant Director, Government Auditing Standards, AIMD, (202) 512–9321.

Dated: November 7, 1997.

Marcia B. Buchanan,

Assistant Director.

[FR Doc. 97–29911 Filed 11–13–97; 8:45 am]

BILLING CODE 1610–02–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Center for Health Statistics (NCHS), Data Policy and Standards Staff; Meeting

Name: ICD–9–CM Coordination and Maintenance (C&M) Committee meeting.

Times and Dates: 9 a.m.–5 p.m. December 4, 1997; 9 a.m.–5 p.m. December 5, 1997.

Place: The Health Care Financing Administration, Auditorium, 7500 Security Boulevard, Baltimore, Maryland.

Status: Open to the public. In the interest of security, non-government employees must show a photo I.D., and sign-in to gain entrance to the building.

Purpose: The ICD–9–CM Coordination and Maintenance Committee will hold its final meeting of the 1997 cycle on Thursday, December 4 (Vol. 3 (Procedures)), and Friday, December 5 (Volumes 1 and 2 (Diagnosis)). The C&M meeting is a public forum for the presentation of proposed modifications to the International Classification of Diseases, Ninth-Revision, Clinical Modification.

Matters To Be Discussed: Agenda items will include:

Injury aftercare status
Palliative care
Ostomy complications
Late effects of CVA
Diabetes
Group B strep carrier status
Complications of artificial skin replacement
Update on ICD–10 Procedure Coding System
Platelet inhibitors
Artificial skin grafts
Stereotactic radiosurgery
Cardiomyostimulator
Percutaneous vascular puncture closure
Amniofusion
Injection or infusion of thrombolytic agent
Addenda

Agenda items are subject to change as priorities dictate.

Contact Person for Additional Information: Amy L. Blum, 301/436–7050 ext. 164 (diagnosis), or Amy Gruber 410/786–1542 (procedures), NCHS, CDC, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782.

Dated: November 7, 1997.

John C. Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–29969 Filed 11–13–97; 8:45 am]

BILLING CODE 4160–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

The National Immunization Program (NIP) of the Centers for Disease Control and Prevention (CDC); Meeting

Name: Adolescent Immunization Meeting.

Time and Date: 7:30 a.m.–4 p.m. December 4, 1997.

Place: J.W. Marriott Hotel, Lenox, 3300 Lenox Road, NE Atlanta, Georgia 30326. Telephone 404/262–3344, fax 404/262–8803.

Status: The meeting is open to the public subject to the availability of conference room space. The meeting will be a round table discussion with public and private medical providers and experts who deal with adolescent health and immunization issues. Written comments will be accepted during the meeting or at the address below. Attendees must provide and pay for their own travel expenses.

Purpose: The meeting will bring together a small group of public and private medical experts, in adolescent health and immunization, to collaborate with the CDC in developing adolescent immunization disease reduction and coverage goals/objectives.

Matters To Be Discussed: CDC speakers will present background information; sample goals/objectives; year 2000 and possible 2010 Healthy People objectives; and other adolescent immunization health information. In addition, CDC speakers will describe vaccine-preventable diseases associated with adolescents and estimated immunization coverage levels.

Specific agenda items include adolescent immunization coverage goals; coverage estimates for childhood and adolescent immunization; adolescent disease reduction goals; epidemiology of vaccine preventable diseases in adolescents; implementation perspectives; HEDIS 3.0 adolescent immunization measures; and managed care organization adolescent immunization policies.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Edith Gary, Health Services Research and Evaluation Branch, Immunization Services Division, CDC, NIP, 1600 Clifton Road, NE, M/S E–52, Atlanta, Georgia 30333. Telephone 404/639–8209, fax 404/639–8615, e-mail exg1@cdc.gov.

Dated: November 7, 1997.

John C. Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–29970 Filed 11–13–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0431]

Iatric Corp.; Revocation of Product License for Coccidioidin, USP (BioCox)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the biological product license issued to Iatric Corp., Tempe, AZ, for the manufacture of Coccidioidin, USP (BioCox). In a letter to FDA dated May 13, 1997, Iatric Corp. voluntarily requested revocation of its product license for Coccidioidin, USP (BioCox). In a letter dated June 25, 1997, FDA informed the firm that its product license for Coccidioidin, USP (BioCox) was revoked.

DATES: The revocation of the product license became effective June 25, 1997.

FOR FURTHER INFORMATION CONTACT: Astrid L. Szeto, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: FDA has revoked the product license issued to Iatric Corp., 2330 South Industry Park Ave., Tempe, AZ 85282, for the manufacture of Coccidioidin, USP (BioCox).

FDA inspected Iatric Corp. on April 7 through 11, 1997. The inspection of the facility revealed serious deviations from applicable Federal regulations. The inspection also included a concurrent investigation concerning the interstate distribution of the product. The deficiencies noted included, but were not limited to, the following: (1) Failure

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