

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-0672]

DWB

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**Iatric Corp.; Revocation of U.S. License No. 0416**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the revocation of the establishment license (U.S. License No. 041 6) and the product license issued to Iatric Corp. for the manufacture of Allergenic Extracts. In letters to FDA dated June 26 and June 30, 1998, the firm voluntarily requested revocation of its establishment and product licenses. In a letter dated August 28, 1998, FDA informed the firm that the establishment and product licenses were revoked.

**DATES:** The revocation of the establishment license (U.S. License No. 0416) and the product license became effective August 28, 1998.

**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 establishment license (U.S. License No. 041 6) and the product license for the manufacture of Allergenic Extracts issued to Iatric Corp., 2330 South Industrial Park Dr., Tempe, AZ 85282.

FDA inspected Iatric Corp. from April 7 through April 11, 1997. The inspection of the facility revealed serious deviations from applicable Federal regulations and the standards established in the fro's license. The deficiencies noted included, but were not limited to, the following: (1) Failure of each person engaged in the manufacture, processing, packing, or holding of a drug product to have the necessary education, training, and experience to perform that person's assigned

functions (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 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 ensure 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 ensure 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) failure to establish and/or follow written procedures for production and process controls designed to ensure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess and to ensure 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)).

These deficiencies demonstrated the 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 21 CFR 600.10(b) and **211.25**. FDA determined that these deficiencies constitute

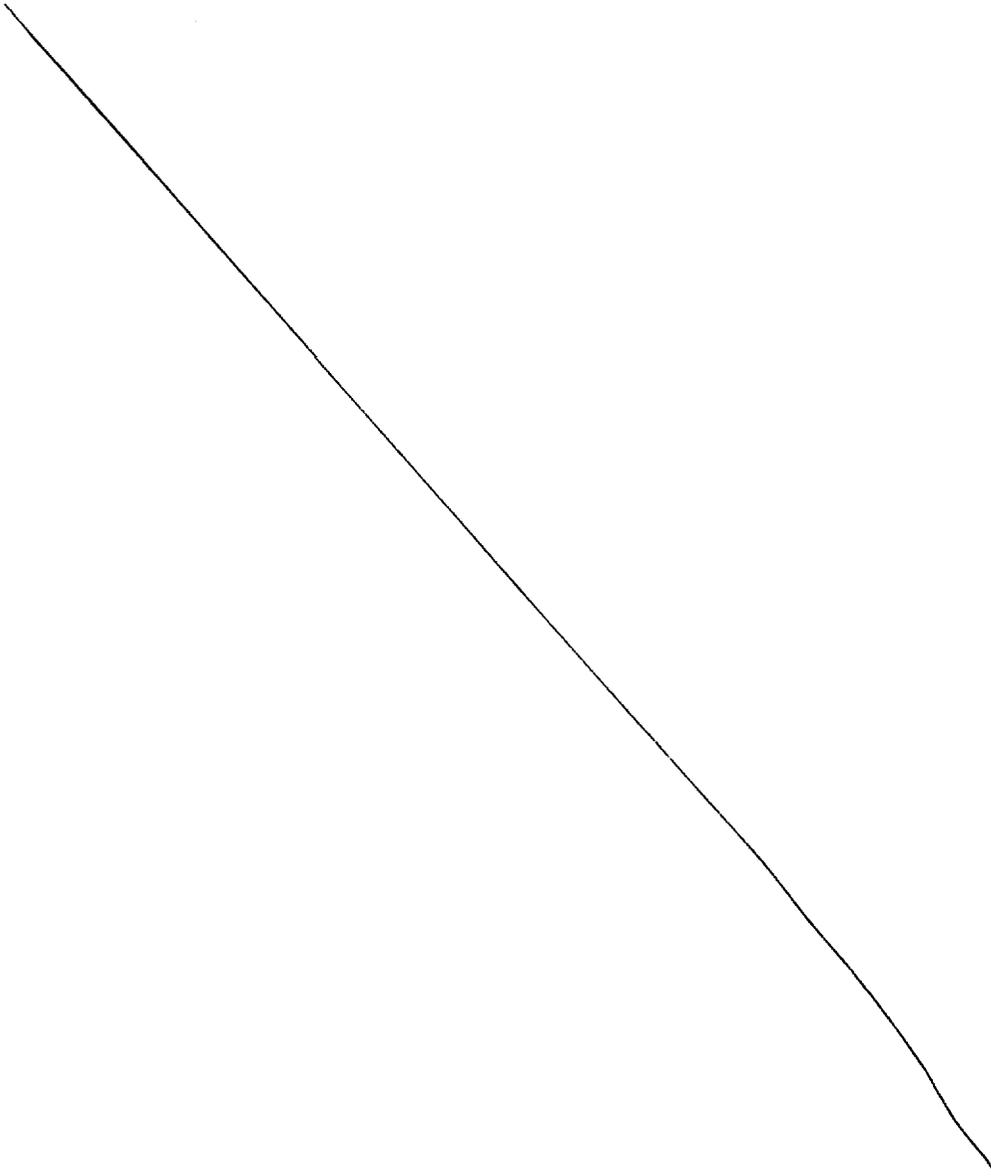
a danger to the public health that warranted suspension under §§ 601.5(b) and 601.6(a) (21 CFR 601.5(b) and 601.6(a)). By letter dated April 25, 1997, to Iatric Corp., FDA suspended the firm's establishment license (U.S. License No. 0416) and product licenses for Coccidioidin U.S.P. and Allergenic Extracts. The letter stated that FDA intended to proceed under § 601.6(b) to revoke the establishment license and the product licenses. By letter dated May 13, 1997, Iatric Corp., voluntarily revoked their product license for Coccidioidin U.S.P. (BioCox). In a letter to FDA dated May 14, 1997, Iatric Corp., requested that the matter of license revocation for Allergenic Extracts be held in abeyance.

In the **Federal Register** of November 14, 1997 (62 FR 61 129), FDA announced the voluntary revocation of the product license for the firm for the manufacturer of Coccidioidin, U.S.P (BioCox), which resulted from the same deficiencies noted previously. In a letter to Iatric Corp., dated June 24, 1998, FDA stated that the extensive failure of the firm to maintain control over the manufacturing process of the licensed products; and the continual failure of the firm, after numerous verbal and written promises, to provide an adequate corrective action plan subsequent to the April 25, 1997, suspension letter demonstrated a distinct pattern of noncompliance with those requirements designed to ensure the safety, purity, identity, and quality of licensed product and, therefore, could no longer grant the firm's May 14, 1997, request that the revocation of license be held in abeyance. In the same letter, FDA provided notice to the firm of FDA's intent to initiate proceedings to revoke all establishment and product licenses encompassed under U.S. License No. 0416 issued to **Iatric Corp.** and to issue a notice of opportunity for hearing under § 601.5(b). In letters dated June 26 and June 30, 1998, **Iatric Corp.** requested voluntary revocation of U.S. License No. 0416, and thereby waived its opportunity for a hearing.

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, 5630 Fishers Lane, rm. 1061, **Rockville**, MD 20852.

These documents are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

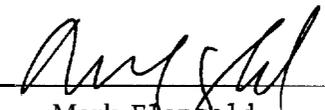
Accordingly, under 21 CFR 601.5(a), section 351 of the Public Health Service Act (42 U.S.C. **262**), and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5. 10) and redelegate to the Director, Center for Biologics Evaluation and Research (21 CFR 5.68), the establishment license (U.S. License No. 0416) and the product license for the manufacture of



Allergenic Extract issued to Iatric Corp., Tempe, AZ 85282, were revoked effective August 28, 1998.

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

Dated: 4/12/99  
April 12, 1999

  
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Mark Elengold  
Deputy Director, Operations  
Center for Biologics  
Evaluation and Research

[FR Dec. 99-???? Filed ??-??-99; 8:45 am]

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