

The Office of Population Affairs is reviewing the family planning services delivery improvement research priorities and may revise those priorities. Accordingly, the November 18, 1985 standing announcement is hereby withdrawn.

**FOR FURTHER INFORMATION CONTACT:**  
Eugenia Eckard, (301) 594-6534.

Dated: April 12, 1999.

**Denese O. Shervington,**

*Deputy Assistant Secretary for Population Affairs.*

[FR Doc. 99-10305 Filed 4-23-99; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Submission for OMB Review; Comment Request

*Title:* Family Preservation and Family Support (FP/FS) Services Implementation Study—State Level Data Collection.

*OMB:* 0970-0137.

*Description:* The Omnibus Budget Reconciliation Act of 1993 (OBRA 93)

established title IV-B, subpart 2 of the Social Security Act (42 U.S.C. 62-628) to provide funds to states for the development of family preservation and family support programs and services. Subpart 2, Section 435 of OBRA 93 requires the Secretary of HHS to evaluate the effectiveness of programs carried out under the legislation. The Adoption and Safe Families Act of 1997, P.L. 105-89, reauthorized the family preservation and family support programs and services and amended Section 431 [42 U.S.C. 629a] to add two new services: Time-Limited Family Reunification Services and Adoption Promotion and Support Services.

In this second phase of data collection, the five data collection instruments, which were used during the previous phase (1996-1999) will be used. Each instrument is geared toward obtaining information from individuals/agencies who will have a slightly different perspective on the context, planning, and implementation of the legislation. The data collection instruments will seek information on the programs and services funded, the goals of the planning process, populations targeted, reform efforts initiated, the relationship between

family preservation, family support and child welfare, staffing and training, information systems.

Data collection on states' planning and implementation experiences will be accomplished through semi-structured interviews with state officials and other key stakeholders who are knowledgeable about child welfare.

Both qualitative and quantitative analyses will be completed to highlight the process states employ to implement the legislation, coordinate with other funding sources, develop new systems, and improve service delivery systems. Data analyses also will focus on the impact of legislative changes on the state implementation of the program and comparisons of state implementation before and after the legislative reauthorization. Information obtained from data analyses will provide feedback to ACF in the determination of future policy guidance and the scope and nature of technical assistance to be provided to states. The information will also provide direct feedback to states concerning successful implementation strategies.

*Respondents:* State, Local or Tribal Government and Not-for-Profit Institutions.

#### ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden house per response	Total burden hours
State Level Data Collection .....	150	1	.0849	127.40

*Estimated Total Annual Burden Hours:* 127.40.

*Additional Information:* Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer.

*OMB Comment:* OMB is required to make a decision concerning the collection of information between 30 to 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget Paperwork Reduction Project, 725 17th Street, N.W., Washington, D.C., 20503, Attn: Ms. Lori Schack.

Dated: April 19, 1999.

**Bob Sargis,**

*Acting Reports Clearance Officer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 99N-0672]

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

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the revocation of the establishment license (U.S. License No. 0416) 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. 0416) 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 firm'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 61129), 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 redelegated 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: April 12, 1999.

**Mark Elengold,**

*Deputy Director, Operations, Center for Biologics Evaluation and Research.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 99F-0187]

### Monsanto Co.; Filing of Food Additive Petition; Correction

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

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of February 8, 1999 (64 FR 6100). The document announced that Monsanto Co. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of L-Phenylalanine, *N*-[*N*-(3,3-dimethylbutyl)-*L*- $\alpha$ -aspartyl]-, 1-methyl ester as a general use sweetener. The name of the additive appeared incorrectly in the **SUMMARY** section. This document corrects that error.

**DATES:** April 26, 1999.

**FOR FURTHER INFORMATION CONTACT:** Blondell Anderson, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3106.

**SUPPLEMENTARY INFORMATION:** In FR Doc. 99-2851, appearing on page 6100 in the **Federal Register** of Monday, February 8, 1999, the following correction is made: