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.

[FR Doc. 99–10289 Filed 4–23–99; 8:45 am]

BILLING CODE 4160–01–F

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*-α-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:

1. On page 6100, in the first column, under the **SUMMARY** section, in line six, ''L-Phenylalanine,*N*-[*N*-(3,3-dimethylbutyl)-*L*-α-aspartyl]-,1-methyl ester'' is corrected to read ''*N*-[*N*-(3,3-dimethylbutyl)-*L*-α-aspartyl]-*L*-phenylalanine 1-methyl ester''.

Dated: March 30, 1999.

Laura M. Tarantino,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 99–10292 Filed 4–23–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–0924]

Food and Drug Administration Modernization Act of 1997; List of Documents Issued by the Food and Drug Administration That Apply to Medical Devices Regulated by the Center for Biologics Evaluation and Research

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of documents issued in response to the Food and Drug Administration Modernization Act of 1997 (FDAMA), and clarifying their applicability to medical devices regulated by the Center for Biologics Evaluation and Research (CBER). This notice is intended to inform the public of the availability of these documents, clarify their scope of applicability, and to provide instructions on ways to access them.

ADDRESSES: Submit written requests for single copies of the document to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your requests, or fax your request to 301–443–8818. The document may also be obtained by fax by calling the CDRH Facts-on-Demand at 1–800–899–0381 or 301–827–0111. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the documents.

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:

I. Background

On November 21, 1997, the President signed into law FDAMA (Pub. L. 105–115). CBER is working closely with CDRH in the implementation of the provisions of FDAMA applicable to medical devices. However, early in the implementation of FDAMA, several documents were issued with explicit applicability to CDRH regulated devices, but for which applicability to CBER regulated devices was unclear. To clarify that these documents are also applicable to medical devices regulated by CBER, FDA is providing the public with this list of documents in section II of this document, acknowledging that the documents are utilized by CBER in its review of medical devices, and providing instructions on ways to access them. The documents in this list are applicable to any device regulated under the medical device amendments of the Federal Food, Drug, and Cosmetic Act (e.g., 510(k) exempt, 510(k), premarket approval). CBER has endorsed these documents and intends to follow the procedures as appropriate.

This list is organized by: (1) Guidances, (2) notices, and (3) rulemakings. Guidance documents that do not have a date and cite of publication in the **Federal Register** were issued directly on the Internet. Although certain documents on the list may reference specific organizational elements and contact points in CDRH, this should not be interpreted to mean that those are also the contact points for CBER. The general contact point in CBER for medical device issues will be the Associate Director for Regulatory Affairs in the Office of Blood Research and Review, CBER.

II. Document References

Name of Document	Date of Issuance[1]	Date of Publication in the FEDERAL REGISTER	FEDERAL REGISTER cite
Guidances			
Guidance on IDE Policies and Procedures[2] (Level 2)	January 20, 1998	N/A	N/A
FDA Modernization Act of 1997: Guidance for the Device Industry on Implementation of Highest Priority Provisions	February 6, 1998	February 6, 1998	63 FR 6193
Determination of Intended Use for 510(k) Devices—Guidance for Industry and CDRH Staff	January 30, 1998	February 25, 1998	63 FR 9570
Guidance on the Recognition and Use of Consensus Standards	February 20, 1998	February 25, 1998	63 FR 9561
Early Collaboration Meetings Under the FDA Modernization Act (FDAMA), Guidance for Industry and CDRH Staff	February 19, 1998	February 25, 1998	63 FR 9570
Guidance on PMA Interactive Procedures for Day-100 Meetings and Subsequent Deficiencies—For Use by CDRH and Industry	February 19, 1998	February 25, 1998	63 FR 9570
30-Day Notices and 135-Day PMA Supplements for Manufacturing Method or Process Changes, Guidance for Industry and CDRH	February 19, 1998	February 25, 1998	63 FR 9570
New Section 513(f)(2)—Evaluation of Automatic Class III Designation, Guidance for Industry and CDRH Staff	February 19, 1998	February 25, 1998	63 FR 9570
Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff	February 19, 1998	February 25, 1998	63 FR 9570
Guidance On Procedures to Determine Application of Postmarket Surveillance Strategies	February 19, 1998	February 25, 1998	63 FR 9571
Guidance on Procedures for Review of Postmarket Surveillance Submissions	February 19, 1998	February 25, 1998	63 FR 9571
Guidance on Medical Device Tracking	February 19, 1998	March 4, 1998	63 FR 10640
PMA/510(k) Expedited Review—Guidance for Industry and CDRH Staff	March 20, 1998	March 31, 1998	63 FR 15427