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

Name of Document	Date of Issuance[1]	Date of Publication in the FEDERAL REGISTER	FEDERAL REGISTER cite
Guidance to Industry Supplements to Approved Applications for Class III Medical Devices: Use of Published Literature, Use of Previously Submitted Materials, and Priority Review	May 20, 1998	May 21, 1998	63 FR 27988
List of Devices for Third Party Review Under the FDA Modernization Act of 1997[2]	February 8, 1999 (list updated periodically)	N/A	N/A
List of Accredited Persons For 510(k) Review under the FDA Modernization Act of 1997[2]	October 2, 1998 (list updated periodically)	N/A	N/A
Guidance for Staff, Industry, and Third Parties: Implementation of Third Party Programs Under the FDA Modernization Act of 1997	October 30, 1998	November 2, 1998	63 FR 58746
Guidance on Criteria and Approaches for Postmarket Surveillance	November 2, 1998	November 3, 1998	63 FR 59315
Guidance for Industry: General/Specific Intended Use	November 4, 1998	November 5, 1998	63 FR 59793
Guidance on Frequently Asked Questions on the Recognition and Use of Consensus Standards[2] (Level 2)	December 21, 1998	N/A	N/A
Notices			
Medical Devices; Exemptions From Premarket Notification; Class II Devices		January 21, 1998	63 FR 3142
Medical Devices; Exemptions From Premarket Notification and Reserved Devices; Class I		February 2, 1998	63 FR 5387
Medical Devices; Device Tracking; New Orders to Manufacturers		March 4, 1998	63 FR 10638
Prompt Review of Supplemental Applications for Approved Devices		May 21, 1998	63 FR 27987
Modifications to the List of Recognized Standards; Availability; Withdrawal of Draft Guidance ''Use of IEC 60601 Standards; Medical Electrical Equipment''		October 16, 1998	63 FR 55617
Rulemakings			
Medical Devices; Reports of Corrections and Removals; Direct Final Rule		August 7, 1998	63 FR 42229
Medical Devices; Reports of Corrections and Removals; Companion to Direct Final Rule; Proposed Rule		August 7, 1998	63 FR 42300
Medical Devices; Exemptions from Premarket Notification ; Class II Devices		November 3, 1998	63 FR 59222
Medical Devices; Exemption from Premarket Notification and Reserved Devices; Class I		November 12, 1998	63 FR 63222
Medical Devices; Investigational Device Exemptions; Final Rule		November 23, 1998	63 FR 64617

[1] The ''Date of Issuance'' is the date that the guidance was announced on the Internet.
[2] Not applicable (N/A)—this document was not announced in the FEDERAL REGISTER. It was issued directly on the Internet.

III. Electronic Access

Persons with access to the Internet may obtain the documents using the World Wide Web (WWW). For WWW access, connect to CBER at ''http://www.fda.gov/cber/guidelines.htm'' for the guidance documents only. Connect to CDRH at ''http://www.fda.gov/cdrh'' for all of the documents listed.

Dated: April 19, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–10290 Filed 4–23–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Biologic Specimen-Based Study of Dietary Measurement Error for Nutritional Epidemiology and Surveillance

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the National Institutes of Health (NIH), National Cancer Institute (NCI) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on June 23, 1998 page 34190–34191 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

Proposed Collection

Title: Biologic specimen-based study of dietary measurement error for nutritional epidemiology and surveillance. *Type of Information Collection Request:* New. *Need and use of Information Collection:* The agency conducts and funds studies examining the relationship between diet and chronic diseases. The study will collection a sample of 400 free-living men and women, 40–69 years of age, two 24-hour dietary recalls, two food frequency questionnaires, a physical activity questionnaire, a dietary screener questionnaire, and an opinion form. Respondents will receive a dose of doubly labeled water and provide spot urine samples to measure energy expenditure, will collect two 24-hour urines to measure urinary nitrogen, and