TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
600.80(c)(1) and (e)	95	146.72	13,938	1	13,938
600.80(c)(2)	95	106.34	10,102	28	282,856
600.81	95	3.57	339	1	339
600.90	12	1	12	1	12
Totals					297, 145

[1] There are no capitol costs or operating and maintenance costs associated with this collection of information.

Under table 2 of this document, the number of respondents is based on the number of manufacturers subject to those regulations. Based on information obtained from CBER?s database system, there were approximately 329 licensed manufacturers of biological products. However, the number of recordkeepers listed for § 600.12(a) through (e) excluding paragraph (b)(2) is estimated to be 111. This number excludes manufacturers of blood and blood components because their burden hours for recordkeeping have been reported under § 606.160 in OMB control number 0910–0116. The total annual records is based on the annual average of lots released (6,747), number of recalls made (1,646) and total number of AER reports received (24,040) in the year 2000 and 2001. The hours per record are based on FDA's experience.

FDA estimates the burden of this recordkeeping as follows:

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Record-keepers	Annual Frequency of Recordkeeping	Total Annual Responses	Hours per Record	Total Hours
600.12	111	60.78	6,747	32	215,904
600.12(b)(2)	329	5.00	1,646	24	39,504
600.80(i)	95	253.05	24,040	1	24,040
Totals					279,448

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: September 27, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–25193 Filed 10–3–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0112]

Agency Information Collection Activities; Announcement of OMB Approval; Regulations Under the Federal Import Milk Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Regulations Under the Federal Import Milk Act'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 18, 2002 (67 FR 47388), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0212. The approval expires on September 30, 2005. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: September 27, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–25192 Filed 10–3–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0062]

Agency Information Collection Activities; Announcement of OMB Approval; Premarket Notification for a New Dietary Ingredient

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Premarket Notification for New Dietary Ingredient'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 10, 2002 (67 FR 39728), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0330. The approval expires on July 31, 2005. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: September 27, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–25194 Filed 10–3–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Docket No. 01D–0202

Medical Devices: The Least Burdensome Provisions of the FDA Modernization Act of 1997; Concept and Principles; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the final guidance entitled ''The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles.'' This final guidance discusses the agency's interpretation of the least burdensome provisions of the Federal Food, Drug, and Cosmetic Act (the act).

DATES: Submit written or electronic comments on the guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles'' to the Division of Small Manufacturers, International and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818.

Submit written comments concerning this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. *See* the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Joanne R. Less, Center for Devices and Radiological Health (HFZ–403), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850 301–594–1190; or Leonard Wilson, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, Bldg. 29B, rm. 5G07, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

A central purpose of the Food and Drug Administration Modernization Act of 1997 (FDAMA) was to ensure the timely availability of safe and effective new products that would benefit the American public. While Congress wanted to reduce unnecessary burdens associated with the premarket clearance and approval processes, Congress did not lower the statutory thresholds for substantial equivalence or reasonable assurance of safety and effectiveness. To help achieve this goal, Congress added section 513(i)(1)(D) and (a)(3)(D)(ii) to the act (21 U.S.C. 360c(i))(l)(D) and (a)(3)(D)(ii). Specifically, section 513(i)(1)(D) states:

> Whenever the Secretary requests information to demonstrate that devices with differing technological characteristics are substantially equivalent, the Secretary shall only request information that is necessary to making substantial equivalence determinations. In making such request, the Secretary shall consider the least burdensome means of demonstrating substantial equivalence and request information accordingly.

Section 513(a)(3)(D)(ii) states that:

> Any clinical data, including one or more well-controlled investigations, specified in writing by the Secretary for demonstrating a reasonable assurance of device effectiveness shall be specified as a result of a determination by the Secretary that such data are necessary to establish device effectiveness. The Secretary shall consider, in consultation with the applicant, the least burdensome appropriate means of evaluating device effectiveness that would have a reasonable likelihood of resulting in approval.

These two paragraphs of section 513 of the law contain what are commonly referred to as the ''least burdensome provisions'' of the act. CDRH worked with its stakeholders to develop an interpretation of the least burdensome provisions that would accurately capture Congress' intent and that could be implemented consistently by the agency and industry. As presented in this final guidance, the agency considers the least burdensome concept to be one that could affect almost all premarket regulatory activities, including presubmission meetings with industry, premarket submissions, and the development of guidance documents and regulations.

The level 1 draft was made available in the **Federal Register** of May 3, 2001 (66 FR 22241), and the 90-day comment period for the draft ended on August 1, 2001. While almost all of the comments strongly supported the guidance and encouraged full implementation of it as soon as possible, several comments included recommendations for the agency. Specifically, it was recommended that FDA develop a training program for its staff on the least burdensome approach as well as ways to assess both the agency's success in implementing the principles and industry's satisfaction with FDA's incorporation of them into its daily activities. The agency agrees with these comments, and its responses to them are discussed in the ''Foreword'' of the guidance.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the least burdensome provisions of the act. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute and regulations.

III. Electronic Access

In order to receive ''The Least Burdensome Provisions of the FDA Modernization Act of 1997; Concept and Principles'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1332) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.