foods. The purpose of this CPG is to provide clear policy and regulatory guidance to FDA's field and headquarters staff. It also contains information that may be useful to the regulated industry and to the public. FDA is issuing this CPG as Level 1 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The guidance represents the agency's current thinking on the subject. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. The guidance is intended to further FDA's efforts to prevent potential serious allergic reactions in sensitive individuals resulting from undeclared allergens in foods. FDA is making this guidance document effective immediately because public participation prior to its implementation is not appropriate in these circumstances (21 CFR 10.115(g)(2); 65 FR 56478). Although the guidance document announced in this notice is being implemented immediately, FDA is requesting comments on the guidance. FDA will review all comments received, revise the guidance in response to the comments as appropriate, and publish a notice of availability if the guidance is revised.

II. Comments

Interested persons may, at any time, submit written comments on the CPG entitled ''Statement of Policy for Labeling and Preventing Cross-Contact of Common Food Allergens,'' to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except

that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the CPG and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Copies of the CPG may also be downloaded to a personal computer with access to the Internet. The Office of Regulatory Affairs (ORA) home page includes the CPG and may be accessed at http://www.fda.gov/ora under ''Compliance References.''

Dated: April 27, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–11072 Filed 5–2–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0202]

Medical Devices: Draft ''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 draft guidance entitled ''The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles.'' In this draft guidance, FDA sets forth its interpretation of the provisions of the Food and Drug Administration Modernization Act of 1997 (FDAMA) that require FDA to take into account the least burdensome means for applicants to demonstrate a device's effectiveness or substantial equivalence. This guidance is neither final nor is it in effect at this time.

DATES: Submit written comments on this draft guidance by August 1, 2001.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled ''The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles'' to the Division of Small Manufacturers 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 on this draft 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. 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.

SUPPLEMENTARY INFORMATION:

I. Background

A central purpose of 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 intend to lower the statutory thresholds for substantial equivalence or reasonable assurance of safety and effectiveness. To help achieve this goal, Congress added section 513(a)(3)(D)(ii) and (i)(1)(D) to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c).

These two paragraphs (a)(3)(D)(ii) and (i)(1)(D) of section 513 of the law contain what are commonly referred to as the ''least burdensome provisions'' of the act. During the last year, FDA has been working with the Least Burdensome Industry Task Force to develop an interpretation of the least burdensome provisions that would accurately capture Congress' intent and that could be implemented consistently by FDA and industry. This draft guidance, in addition to the other guidances developed by the agency, is a part of that process. As presented in this draft guidance, FDA has chosen to apply the least burdensome concept beyond the two statutory provisions in which the language actually appears. FDA 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.

II. Significance of Guidance

This draft guidance document 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 statutes and regulations.

The agency has adopted good guidance practices (GGPs), and published the final rule, which set forth the agency's regulations for the development, issuance, and use of guidance documents (21 CFR 10.115; 65 FR 56468, September 19, 2000). This draft guidance document is issued as a Level 1 guidance in accordance with the GGP 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.

Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. Guidance documents are also available on the Dockets Management Branch Web site at http://www.fda.gov/ohrms/ dockets/ default.htm.

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance by August 1, 2001. Submit two copies of any comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 30, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01–11231 Filed 5–1–01; 12:40 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–116]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Clinical Laboratory Improvement Amendments (CLIA) Application Form and Supporting Regulations in 42 CFR 493.1—.2001; *Form No.:* HCFA–116 (OMB# 0938–0581); *Use:* Certification requirements have been established for any entity that performs testing on human beings for diagnostic or treatment purposes. Laboratories must apply for and obtain a certificate in order to perform this testing; *Frequency:* Biennially; *Affected Public:* Business or other for profit, Not for profit institutions, Federal Government, and State, local or tribal government; *Number of Respondents:* 16,000; *Total Annual Responses:* 16,000; *Total Annual Hours:* 20,000.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/ regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Julie Brown, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: April 23, 2001.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Standards and Support Group, Division of HCFA Enterprise Standards.

[FR Doc. 01–11044 Filed 5–2–01; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–18]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a curently approved collection; *Title of Information Collection* Application for Hospital Insurance in 42 CFR 406.7; *Form No.:* HCFA–18 (OMB# 0938–0251); *Use:* The HCFA–18F5 is used to establish entitlement to hospital insurance and supplementary medical insurance for beneficiaries entitled under title XVIII of the Social Security Act; *Frequency:* On occasion; *Affected Public:* Individuals or households; *Number of Respondents:* 50,000; *Total Annual Responses:* 50,000; *Total Annual Hours:* 12,500.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at *http://www.hcfa.gov/ regs/prdact95.htm*, or E-mail your request, including your address, phone