be found on the following Web site: http://www.nih.gov/grants/funding/phs398/phs398.html. The forms can be found at http://www.nih.gov/grants/funding/phs398/forms__toc.html. Applicants are advised that FDA does not adhere to the page limitations or the type size and line spacing requirements imposed by NIH on its applications.

B. Format for Application

Submission of the application must be on Grant Application Form PHS 398 (Rev. 4/98). All ''General Instructions'' and ''Specific Instructions'' in the application kit should be followed with the exception of the receipt dates and mailing label address. The face page of the application should reflect the request for applications number RFA–FDA–CFSAN–2001–2.

Data included in the application, if restricted with the legend specified below, may be entitled to confidential treatment as trade secret or confidential commercial information within the meaning of the Freedom of Information Act (5 U.S.C. 552(b)(4)) and FDA's implementing regulations (21 CFR 20.61).

Information collection requirements requested on Form PHS 398 and the instructions have been submitted by PHS to the Office of Management and Budget (OMB) and were approved and assigned OMB control number 0925–0001.

C. Legend

Unless disclosure is required by the Freedom of Information Act as amended (5 U.S.C. 552) as determined by the freedom of information officials of DHHS or by a court, data contained in the portions of this application that have been specifically identified by page number, paragraph, etc., by the applicant as containing restricted information shall not be used or disclosed except for evaluation purposes.

Dated: April 30, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01–11159 Filed 5–2–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Anesthetic and Life Support Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Anesthetic and Life Support Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 14 and 15, 2001, 8 a.m. to 5 p.m.

Location: Holiday Inn, The Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Contact: Kimberly Topper, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville MD 20857, 301–827–7001, e-mail: topperk@cder.fda.gov, FAX 301–827–6801, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12529. Please call the Information Line for up-to-date information on this meeting.

Agenda: On both days the committee will discuss the medical use of opiate analgesics in various patient populations, including pediatric patients and patients with chronic pain of nonmalignant etiology, as well as the risk to benefit ratio of extending opiate treatment into these populations. It will also address concerns regarding the abuse potential, diversion and increasing incidence of addiction to opiate analgesics, especially to the modified release opiate analgesics.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by June 7, 2001. Oral presentation from the public will be scheduled between approximately 1 p.m. and 2 p.m each day. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 7, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Background material from FDA will be posted 24 hours before the meeting at the Anesthetic and Life Support Drugs Advisory Committee docket site at http://www.fda.gov/ohrms/dockets/ac/acmenu.htm. (Click on the year 2001 and scroll down to Anesthetic and Life Support Drugs meetings.) This is the same Web site where you can find the minutes, transcript, and slides from the meeting. This material is generally posted about 3 weeks after the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 27, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–11157 Filed 4–30–01; 4:16 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0184]

Compliance Policy Guide: ''Statement of Policy for Labeling and Preventing Cross-Contact of Common Food Allergens;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a compliance policy guide (CPG) entitled ''Statement of Policy for Labeling and Preventing Cross-Contact of Common Food Allergens.'' This CPG is intended to set forth FDA's internal enforcement priorities concerning undeclared food allergens.

DATES: Submit written comments on this CPG at any time.

ADDRESSES: Submit written requests for single copies of the CPG entitled ''Statement of Policy for Labeling and Preventing Cross-Contact of Common Food Allergens'' to the Director, Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–827–0482. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the document.

Submit written comments on the CPG to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Technical questions concerning allergens in foods: Kathy Gombas, Office of Field Programs (HFS–615), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4231, FAX 202–260–0136.

Questions concerning regulatory actions: MaryLynn Datoc, Office of Enforcement (HFC–230), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0413, FAX 301–827–0482.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has developed a CPG on FDA's internal enforcement process concerning undeclared allergens in

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