the product as these factors may relate to the safety or effectiveness of the product. The applicant must obtain approval of a supplement from FDA prior to distribution of a product made using the change.

Based on data concerning the number of supplements received by the agency, FDA estimates that approximately 1,517 supplements will be submitted annually under section 506A(c)(1) and (c)(2) of the act. FDA estimates that approximately 263 applicants will submit such supplements, and that it will take approximately 150 hours to prepare and submit to FDA each supplement.

Section 506A(d)(1)(B), (d)(1)(C), and (d)(3)(B)(i) sets forth requirements for changes requiring supplement submission at least 30 days prior to distribution of the product made using the change (moderate changes). Under these sections, a supplement must be submitted for any change in the product, production process, quality controls, equipment, or facilities that has a moderate potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product as these factors may relate to the safety or effectiveness of the product. Distribution of the product made using the change may begin not less than 30 days after receipt of the supplement by FDA.

Based on data concerning the number of supplements received by the agency, FDA estimates that approximately 2,322 supplements will be submitted annually under section 506A(d)(1)(B), (d)(1)(C), and (d)(3)(B)(i) of the act. FDA estimates that approximately 274 applicants will submit such supplements, and that it will take approximately 95 hours to prepare and submit to FDA each supplement.

Under section 506A(d)(3)(B)(ii) of the act, FDA may designate a category of changes for the purpose of providing that, in the case of a change in such category, the holder of an approved application may commence distribution of the drug upon receipt by the agency of a supplement for the change. Based on data concerning the number of supplements received by the agency, FDA estimates that approximately 1959 supplements will be submitted annually under section 506A(d)(3)(B)(ii) of the act. FDA estimates that approximately 202 applicants will submit such supplements, and that it will take approximately 95 hours to prepare and submit to FDA each supplement.

Section 506A(d)(1)(A), (d)(1)(C), (d)(2)(A), and (d)(2)(B) of the act sets forth requirements for changes to be described in an annual report (minor changes). Under these sections, changes in the product, production process, quality controls, equipment, or facilities that have a minimal potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product as these factors may relate to the safety or effectiveness of the product must be documented by the applicant in the next annual report.

Based on data concerning the number of supplements and annual reports received by the agency, FDA estimates that approximately 7,639 annual reports will include documentation of certain manufacturing changes as required under section 506A(d)(1)(A), (d)(1)(C), (d)(2)(A), and (d)(2)(B). FDA estimates that approximately 580 applicants will submit such information and that it will take approximately 35 hours to prepare and submit to FDA the information for each annual report.

Dated: December 16, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–31412 Filed 12–17–03; 1:28 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Dermatologic and Ophthalmic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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 Committees: Drug Safety and Risk Management Advisory Committee and the Dermatologic and Ophthalmic 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 February 26 and 27, 2004, from 8 a.m. to 5 p.m.

Location: Hilton, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Shalini Jain, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301–827–7001, e-mail: *jains@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), codes 3014512535 or 3014512534. Please call the Information Line for up-to-date information on this meeting.

The background materials for this meeting will become available no later than 1 business day before the meeting and will be posted at: *www.fda.gov/ohrms/dockets/ac/acmenu.htm*. (Click on the year 2003 and scroll down to either the Drug Safety and Risk Management Advisory Committee or the Dermatologic and Ophthalmic Drugs Advisory Committee meetings.)

Agenda: The committee will discuss the following topics: (1) The effectiveness of the isotretinoin risk management program for the prevention of fetal exposure to ACCUTANE and its generic equivalents, and (2) consider whether changes to this isotretinoin risk management program would be appropriate.

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 February 16, 2004. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon on February 26, 2004, and between approximately 8:30 a.m. and 9:30 a.m. on February 27, 2004. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 16, 2004, 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.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Shalini Jain at least 7 days in advance of the meeting.

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

Dated: December 15, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03–31385 Filed 12–18–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants (Ranch Hand Advisory Committee); Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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: Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants (Ranch Hand Advisory Committee).

General Function of the Committee: To advise the Secretary and the Assistant Secretary for Health concerning its oversight of the conduct of the Ranch Hand Study by the U.S. Air Force and provide scientific oversight of the Department of Veterans Affairs Army Chemical Corps Vietnam Veterans Health Study, and other studies in which the Secretary or the Assistant Secretary for Health believes involvement by the committee is desirable.

Date and Time: The meeting will be held on January 21, 2004, 8 a.m. to 3:30 p.m.

Location: Food and Drug Administration, 5630 Fishers Lane, rm. 1066, Rockville, MD 20857.

Contact Person: Leonard Schechtman, National Center for Toxicological Research (HFT–10), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6696, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512560. Please call the Information Line for up-to-date information on this meeting.

Agenda: The U.S. Air Force will provide a program management update and present information on the following topics: Syndrome X; cancer and hepatitis in the comparison group vs. years in Southeast Asia; prostate cancer; adipose tissue study results; and memory loss and end of study transition.

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 January 9, 2004. Oral presentations from the public will be scheduled between approximately 1:30 p.m. to 2:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 6, 2004, 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.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Leonard Schechtman at least 7 days in advance of the meeting.

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

Dated: December 15, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03–31386 Filed 12–18–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D–0525]

Guidance for Industry and FDA Staff; Premarket Notification Submissions for Chemical Indicators; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Premarket Notification [510(k)] Submissions for Chemical Indicators.'' The document provides guidance for industry and other interested parties regarding the submission of chemical indicators such as process indicators, chemical integrators, and air removal indicators used in test packs.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Premarket Notification [510(k)] Submissions for Chemical Indicators'' 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. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Chiu Lin, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8913, ext. 143.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance is for chemical indicators intended for use in health care facilities. Chemical indicators are Class II devices identified in 21 CFR 880.2800. The chemical indicators discussed in the guidance document include process indicators, chemical integrators, and air removal indicators used in test packs such as the Bowie Dick Test Pack.

In the **Federal Register** of January 27, 2003 (68 FR 3887), FDA invited interested persons to comment by April 28, 2003, on the draft guidance entitled ''Chemical Indicators Premarket Notification [510(k)] Submissions; Draft Guidance for Industry and FDA.'' FDA received one comment. FDA considered the comment and revised the guidance document for clarity.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices (GGPs) regulation (21 CFR 10.115). The guidance represents the agency's current thinking on chemical