C–South, 120 South Saint Joseph St., South Bend, IN.

*Contact*: Keith J. Jasukaitis, Food and Drug Administration, 1560 East Jefferson Ave., Detroit, MI 48207, 313–226–6260, ext. 114, FAX 313–226–3076, or e-mail ''kjasukai@ora.fda.gov''.

*Registration*: Send registration information (including name, title, firm name, address, telephone, and fax number, and the number of people expected to attend) to the contact person by Friday, October 23, 1998.

If you need special accommodations due to a disability, please notify Keith J. Jasukaitis by October 23, 1998.

Dated: September 11, 1998.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 98–25109 Filed 9–18–98; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Advisory Committee for Pharmaceutical Science; 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 for Pharmaceutical Science.

*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 October 22, 1998, 8:30 a.m. to 5 p.m.

*Location*: Advisory Committee conference room, rm. 1066, 5630 Fishers Lane, Rockville, MD 20852.

*Contact Person*: Kimberly L. Topper or Angie Whitacre, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857–1000, 301–827–7001, or e-mail ''Topperk@cder.fda.gov'', or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12539. Please call the Information Line for up-to-date information on this meeting.

*Agenda*: The committee will discuss: (1) Bioavailability/bioequivalence (BA/BE) issues related to solid oral dosage forms; (2) progress reports on guidances pertaining to the biopharmaceutical classification system, other BA/BE guidances; and (3) criteria (average, population, and individual) to allow comparison of BE measures/parameters.

*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 October 5, 1998. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 5, 1998, 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.

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

Dated: September 11, 1998.

**Sharon Smith Holston,**

*Acting Commissioner of Food and Drugs.*

[FR Doc. 98–25106 Filed 9–18–98; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Joint Meeting of the Advisory Committee for Pharmaceutical Science 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*: Advisory Committee for Pharmaceutical Science 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 October 23, 1998, 8:30 a.m. to 5 p.m.

*Location*: Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD 20852.

*Contact Person*: Kimberly L. Topper or Tracy Riley, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or e-mail ''Topperk@cder.fda.gov'', or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12539. Please call the Information Line for up-to-date information on this meeting.

*Agenda*: The committees will discuss: (1) The draft guidance entitled ''Topical Dermatological Drug Product NDA's and ANDA's—In Vivo Bioavailability, Bioequivalence, In Vitro Release and Associated Studies;'' (2) public comments received on the draft guidance; and (3) additional information.

*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 October 5, 1998. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 5, 1998, 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.

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

Dated: September 11, 1998.

**Sharon Smith Holston,**

*Acting Commissioner of Food and Drugs.*

[FR Doc. 98–25107 Filed 9–18–98; 8:45 am]

**BILLING CODE 4160–01–F**

## 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 Department of Health and Human

Services. 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 Air Force and provide scientific oversight of the Department of Veterans Affairs (VA) 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 October 26, 1998, 1 p.m. to 5:30 p.m., and October 27, 1998, 8:30 a.m. to 5 p.m.

*Location*: Holiday Inn Riverwalk, 217 North St. Marys St., Tarantella Room, rm. 4, San Antonio, TX.

*Contact Person*: Ronald F. Coene, 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 12560. Please call the Information Line for up-to-date information on this meeting.

*Agenda*: On October 26, 1998, the VA will present an overview and data collection issues from the pilot study of the Army Chemical Corps Vietnam Veterans Health Study, and discuss considerations for the main health study. On October 27, 1998, the Air Force Health Study presentations will: (1) Provide Cycle 5 Health Exam information, summary, status, and proposed schedule for committee review; (2) report on the latest findings, as well as the status of special studies on half-life, adipose tissue analysis, glucose clamp, and multiple analyte; (3) present proposed measurements for the Cycle 6 Health Exam; (4) report the status of scanning and records maintenance; (5) present a summary of the biological archive; (6) discuss the release of the 1984 preliminary birth defects report; and (7) present the status of public release data.

*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 October 16, 1998. On October 26, 1998, oral presentations from the public will be scheduled between approximately 4:30 p.m. and 5:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 16, 1998, 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.

The Commissioner approves the scheduling of meetings at locations outside of the Washington, DC, area on the basis of the criteria of 21 CFR 14.22 of FDA's regulations relating to public advisory committees.

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

Dated: September 11, 1998.

**Sharon Smith Holston,**

*Acting Commissioner of Food and Drugs.*

[FR Doc. 98–25112 Filed 9–18–98; 8:45 am]

BILLING CODE 4160–01–F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 98D–0656]**

### Draft Guidance for Industry on Submission of Abbreviated Reports and Synopses in Support of Marketing Applications; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Submission of Abbreviated Reports and Synopses in Support of Marketing Applications.'' This draft guidance, which implements section 118 of the Food and Drug Administration Modernization Act of 1997 (Modernization Act), is intended to assist applicants who wish to submit abbreviated reports and synopses in lieu of full reports for certain clinical studies, both in marketing applications for new products and in supplements to approved applications. The draft guidance describes which studies may be submitted as abbreviated reports or synopses and describes a format for such submissions. In addition to seeking general comments on the draft guidance, FDA is soliciting comment on three specific issues related to certain types of study submissions and their formats.

**DATES:** Written comments may be submitted on the draft guidance by November 20, 1998. General comments on the agency guidance documents are welcome at any time.

**ADDRESSES:** Copies of this draft guidance for industry are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm'' or ''http://www.fda.gov/cber/guidelines.htm''. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 or the Manufacturers Assistance and Communication Staff (HFM–42), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments are to be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Debbie J. Henderson, Center for Drug Evaluation and Research (HFD–6), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–6779.

**SUPPLEMENTARY INFORMATION:** FDA is announcing the availability of a draft guidance for industry entitled ''Submission of Abbreviated Reports and Synopses in Support of Marketing Applications.'' Section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)) provides that full reports of the investigations used to demonstrate a product's safety and effectiveness be submitted in a new drug application (NDA). Similarly, for biologics license applications (BLA's) FDA often requires that a manufacturer submit full reports to demonstrate that the biological product is safe, pure, and potent.

Section 118 of the Modernization Act, ''Data requirements for drugs and biologics,'' directs FDA to issue guidance on when abbreviated study reports may be submitted in NDA's and BLA's in lieu of full reports. This draft guidance is intended to fulfill the requirements of section 118 of the Modernization Act by providing guidance on the types of studies that may be submitted in abbreviated reports or synopses. This draft guidance also provides recommendations on the formats that should be used.