p.m. and 2 p.m. on April 5, 2001, and between approximately 11 a.m. to 11:30 a.m. on April 6, 2001. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 26, 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.

Closed Committee Deliberations: On April 5, 2001, from 5:15 p.m. to 6 p.m. the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 5552b(c)(6)). The committee will discuss reports of the review of research programs in the Division of Cellular and Gene Therapies and the Division of Monoclonal Antibodies, Center for Biologics Evaluation and Research.

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

Dated: March 12, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–6774 Filed 3–19–01; 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 (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 April 5, 2001, 8:30 a.m. to 4:30 p.m.

Location: Parklawn Bldg., 5600 Fishers Lane, conference room B, third floor, Rockville, MD.

Contact: Leonard M. Schechtman, Food and Drug Administration, 5600 Fishers Lane, rm. 16–53, 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: The committee will review four research proposals and provide comments and recommendations to the U.S. Air Force. The proposals are concerned with measurements of: (1) Carotid intima-media thickness, (2) peripheral blood pressure, (3) nerve conduction velocity, and (4) archiving blood cells for future measurements of Ah receptor polymorphisms.

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 March 26, 2001. Oral presentations from the public will be scheduled on April 5, 2001, 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 March 26, 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.

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

Dated: March 12, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–6776 Filed 3–19–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0049]

Guidance on Reduction of Civil Money Penalties for Small Entities; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing the final guidance entitled ''Reduction of Civil Money Penalties for Small Entities'' as required by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) and the Presidential Memorandum of April 21, 1995.

DATES: The final guidance is effective April 19, 2001. Written comments may be submitted at any time.

ADDRESSES: Submit written comments on the final 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 written requests for single copies of the final guidance to the Division of Compliance Policy (HFC–230), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or fax your request to 301–827–0482. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the final guidance.

FOR FURTHER INFORMATION CONTACT: Jeffrey B. Governale, Division of Compliance Policy (HFC–230), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0411, FAX 301–827–0482.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is issuing a final guidance for the reduction of civil money penalties (CMP's) for small entities (penalty reduction guidance) as mandated by SBREFA (Public Law 104–121) and the Presidential Memorandum of April 21, 1995 (60 FR 20621, April 26, 1995). SBREFA was enacted on March 29, 1996, and seeks to improve the regulatory climate for small entities by, among other things, requiring agencies to establish small entity penalty reduction policies. The Presidential Memorandum of April 21, 1995, directs agencies to use their discretion to