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

modify the penalties for small businesses in certain situations.

FDA currently enforces the following amendments to the Federal Food, Drug, and Cosmetic Act (21 U.S.C.) and the Public Health Service Act (42 U.S.C.), which authorize CMP's under the referenced sections:

Radiation Control for Health and Safety Act of 1968 (21 U.S.C. 360pp),

Safe Medical Devices Act of 1990 (21 U.S.C. 333(f)),

Mammography Quality Standards Act of 1992 and the Mammography Quality Standards Reauthorization Act of 1998 (42 U.S.C. 263b(h)),

National Childhood Vaccine Injury Act of 1986 (42 U.S.C. 262(d)(2) and 42 U.S.C. 300aa–28),

Prescription Drug Marketing Act of 1988 (21 U.S.C. 333(b)),

Generic Drug Enforcement Act of 1992 (21 U.S.C. 335b), and

Food Quality Protection Act of 1996 (21 U.S.C. 333(f)).

In the **Federal Registers** of May 18 and June 15, 1999 (64 FR 26984 and 32059, respectively), FDA issued a draft civil money penalty reduction policy for small entities. One trade association submitted comments to the docket. FDA reviewed and evaluated all of the comments and, in response, made appropriate changes to the final penalty reduction guidance.

In addition to the comments, SBREFA, and the April 21, 1995, Presidential memorandum discussed above, FDA has reviewed: (1) The Federal statutes it enforces which authorize CMP's, and (2) its current practices used to assess CMP's on small entities. On the basis of that review, FDA is announcing its final penalty reduction guidance for small entities.

II. Statutory and Regulatory Requirements

This penalty reduction guidance shall not supersede or negate any applicable statutory or regulatory requirements. For example in device and food cases, in determining the amount of a CMP and any modification, the agency shall comply with 21 U.S.C. 333(f). Subsequently, this penalty reduction guidance would then be applied to small entities.

III. Significance of Guidance

This guidance document represents the agency's current thinking on the reduction of CMP's for small entities. 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 requirements of the applicable statute and regulations.

The agency has adopted good guidance practices (GGP's), which set forth the agency's regulation for the development, issuance, and use of guidance documents (65 FR 56468, September 19, 2000). This final guidance document is issued as a Level 1 guidance consistent with GGP's.

IV. Comments

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the final guidance document entitled ''Reduction of Civil Money Penalties for Small Entities.'' 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. Such comments will be considered when determining whether to amend the current guidance. Copies of the final guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

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

Dated: February 22, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–6775 Filed 3–19–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel.

Date: March 21, 2001.

Time: 2 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Natcher Building, 45 Center Drive, Room 1AS19, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Rebecca H. Johnson, PhD, Scientific Review Administrator, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 1AS19J, Bethesda, MD 20892, (301) 594–2771, johnsonrh@nigms.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel Post Doctoral Training.

Date: March 28, 2001.

Time: 1:15 p.m. to 2:45 p.m.

Agenda: To review and evaluate grant applications.

Place: Natcher Building, 45 Center Drive, Room 1AS–13, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Arthur L. Zachary, PhD, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 1AS–13H, Bethesda, MD 20892, (301) 594–2886, zacharya@nigms.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: March 13, 2001.

Anna P. Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–6901 Filed 3–19–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as