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]

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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]

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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