DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Scientific Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that on February 5, 1999, a Research Integrity Adjudications Panel of the HHS Departmental Appeals Board issued a ruling upholding the scientific misconduct finding of the Office of Research Integrity (ORI) in the following case:

Kimon J. Angelides, Ph.D., Baylor College of Medicine. On the basis of the report of an investigation conducted by Baylor College of Medicine and information obtained by ORI during its oversight review, ORI found on March 10, 1997, that Dr. Angelides, former Professor, Department of Molecular Physiology and Biophysics and Department of Cell Biology, Baylor College of Medicine, engaged in scientific misconduct by intentionally falsifying data and misrepresenting research results in five grant applications submitted to the National Institutes of Health (NIH) and in five papers published while he was at the Baylor College of Medicine. The research involved the study of the voltage-gated sodium channel protein in nervous tissue and its location in myelinated nerves. In a decision dated February 5, 1999, the HHS Departmental Appeals Board affirmed ORI’s findings of scientific misconduct and determined that the administrative actions recommended by ORI were justified. The following actions have been implemented:

(1) Dr. Angelides has been barred from eligibility for, or involvement in, nonprocurement transactions (e.g., grants and cooperative agreements) of the Federal Government and from contracting or subcontracting with any Federal Government agency for a period of five (5) years, beginning on February 22, 1999.

(2) Dr. Angelides is prohibited from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of five (5) years, beginning on February 22, 1999.

(3) Within 30 days of February 22, 1999, Dr. Angelides is required to submit a letter to the editors of Proceedings of the Royal Society of London, Annals of the New York Academy of Science, Glia, and Proceedings of the National Academy of Science (USA) requesting retraction of the falsified figures and text in each of the following scientific papers:


A retraction of the following scientific paper already has been published (Brain Research 761(2), 1997) at the request of the coauthors:


FOR FURTHER INFORMATION CONTACT: Acting Director, Division of Research Investigations, Office of Research Integrity, 5515 Security Lane, Suite 700, Rockville, Maryland 20852, (301) 443–5330.

Chris B. Pascal, Acting Director, Office of Research Integrity.

[FR Doc. 99–6077 Filed 3–11–99; 8:45 am]

BILLING CODE 4160–17–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0254]

Draft Guidance for Industry on Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling; 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 “Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling.” This draft guidance modifies a previous guidance issued by the Division of Drug Marketing, Advertising, and Communications (DDMAC). It documents the applicability of the previous guidance to animal prescription drugs and biologic products.

DATES: Written comments on the draft guidance may be submitted by May 11, 1999.

ADDRESSES: Submit written requests for single copies of the draft guidance for industry entitled “Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling” to: (1) The Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or (2) the Office of Communications, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 5630 Fawcett Road, Rockville, MD 20852–1448; or (3) the Communication Staff, Center for Veterinary Medicine, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist the office in processing your requests. Submit written comments on this draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Standish Pl, Rockville, MD 20855. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT:

For information on the content of the draft guidance: Mélissa M. Moncavage, Center for Drug Evaluation and Research (HFD–40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2828, e-mail “moncavage@cdr.fda.gov”; or Toni M. Stifano, Center for Biologics Evaluation and Research (HFM–602), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3028, e-mail “stifano@1.cber.fda.gov”; or Mukund R. Parkhie, Center for Veterinary Medicine (HFV–216, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–6642, e-mail “mparkhie@bangate.fda.gov”.

SUPPLEMENTARY INFORMATION:
I. Background

DDMAC is currently reissuing guidances pertaining to prescription drug advertising and promotional labeling. These guidances have been issued to the pharmaceutical industry at various times since 1970, usually as letters or guidance papers. In the Federal Register of March 28, 1997 (62 FR 14912), FDA published a notice listing all previous guidances and indicating whether the agency believed they were obsolete or needed revision. Under section II.B.3 of that document, FDA listed a guidance, issued in April 1994, that needed revision. The guidance addressed placement, size, and prominence of the proprietary (brand) name and established (generic) name in advertising and labeling of prescription drug products.

This draft revision of that guidance for industry is entitled "Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling." It has been revised in the following ways: (1) It modifies the format of the guidance issued in April 1994; (2) it adds new sections to discuss the applicability of the guidance to audiovisual, broadcast, and computer-based advertisements, and promotional labeling; (3) it adds a new section to discuss the placement, size, and prominence of the proprietary (brand) name and established (generic) name for products with two or more active ingredients; and (4) it documents the applicability of this guidance to animal prescription drugs and biologic products.

This draft guidance for industry represents the agency's current thinking on proprietary and established name placement, size, and prominence in advertising and promotional labeling. 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 requirement of the applicable statute, regulations, or both.

II. Electronic Access

Copies of this draft guidance are available on the Internet at "http://www.fda.gov/cder/guidance/index.htm" or "http://www.fda.gov/cber/guidelines.html" or "http://www.fda.gov/cvm".

III. Comments

Interested persons may, on or before May 11, 1999, submit to the Dockets Management Branch (address above) written comments on the draft guidance. 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. The draft guidance and received comments are available for public examination in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 5, 1999.

William K. Hubbard,
Acting Deputy Commissioner for Policy.

[F.R. Doc. 99–6118 Filed 3–11–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health;
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 Mental Health Special Emphasis Panel.

Date: March 9, 1999.

Time: 1:00 PM to 2:30 PM.

Agenda: To review and evaluate grant applications.

Place: Parklawn Building—Room 9C–26, 5600 Fishers Lane, Rockville, MD 20857, (Telephone Conference Call).

Contact Person: LaVerne Y. Stringfield, Committee Management Officer, NIH.


BILLING CODE 4140–01–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Federal Property Suitable as Facilties To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

EFFECTIVE DATE: March 12, 1999.

FOR FURTHER INFORMATION CONTACT: Mark Johnston, Department of Housing and Urban Development, Room 7256, 545 Seventh Street SW, Washington, DC 20410; telephone (202) 708–1226; TTY number for the hearing- and speech-impaired (202) 708–2565, (these telephone numbers are not toll-free), or call the toll-free Title V information line at 1–800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with the December 12, 1988 court order in National Coalition for the Homeless v. Veterans Administration, No. 88–2503–OG (D.D.C.), HUD publishes a Notice, on a weekly basis, identifying unutilized, excess and surplus Federal buildings and real property that HUD has reviewed for suitability for use to assist the homeless. Today's Notice is for the purpose of announcing that no additional properties have been determined suitable or unsuitable this week.