

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:

Kimion J. Angelides, Ph.D., Baylor College of Medicine: Based on 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 debarred 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:

- Black, J.A., Friedman, B., Waxman, S.G., Elmer, L.W., and Angelides, K.J. "Immuno-ultrastructural localization of sodium channels at nodes of Ranvier and perinodal astrocytes in rat optic nerve." *Proc. R. Soc. London* 238:39–51, 1989.
- Minturn, J.E., Sontheimer, H., Black, J.A., Angelides, K.J., Ransom, B.R., Ritchie, J.M., and Waxman, S.G. "Membrane-associated sodium channels and cytoplasmic precursors in glial cells." *Ann. N.Y. Acad. Sci.* 633:255–271, 1991.
- Black, J.A., Waxman, S.G., Friedman, B., Elmer, L.W., and Angelides, K.J. "Sodium channels in astrocytes of rat optic nerve in situ: Immuno-electron microscopic studies." *Glia* 2:353–369, 1989.
- Ritchie, J.M., Black, J.A., Waxman, S.G., and Angelides, K.J. "Sodium channels in the cytoplasm of Schwann cells." *Proc. Natl. Acad. Sci. (USA)* 87:9290–9294, 1990.

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

- Elmer, L.W., Black, J.A., Waxman, S.G., and Angelides, K.J. "The voltage dependent sodium channel in mammalian CNS and PNS: Antibody characterization and immunocytochemical localization." *Brain Research* 532:222–231, 1990.

FOR FURTHER INFORMATION CONTACT:

Acting Director, Division of Research Investigations, Office of Research Integrity, 5515 Security Lane, Suite 700, Rockville, MD 20852, (301) 443–5330.

Chris B. Pascal,

Acting Director, Office of Research Integrity.

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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, 1401 Rockville Pike, 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 Fishers Lane, rm. 1061, Rockville, MD 20852. 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: Melissa 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@cder.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@A1.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: