FDA invites ATA, TES & AACE to Plan Workshop on Thyroxine Bioequivalence

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NOV 0 5 2003

American Thyroid Association
Attention: Paul W. Ladenson, M.D.
President-Elect
6066 Leesburg Pike, Suite 650
Falls Church, VA 22041

Dear Dr. Ladenson,

Thank you for your letter of October 1, 2003 regarding the recent meeting between the Food and Drug Administration (FDA) and the American Thyroid Association on September 16, 2003.

We would like to thank you for your participation in this meeting and your commitment to this important public health issue. We also appreciate your willingness to help draft the agenda and propose a list of participants that could contribute to a workshop program that the FDA proposes. We would like to have the issues that we raised at our meeting discussed in a workshop setting.

As stated in your letter, we are committed to plan and hold a workshop of sufficient depth and duration. At that workshop we plan to address all of the relevant issues raised at our meeting: bioequivalence testing baseline correction, optimal test subjects, and acceptable confidence limits; and TSH as a pharmacodynamic measure.

We acknowledge the concerns raised at the meeting and in your letter regarding the thyroxine dose precision and limitations in current bioequivalence standard. We will take your concerns into consideration when reviewing these applications.

If you have any further inquiries or information to provide that would be useful in the development of the workshop, please feel free to contact Anne Henig, at 301-594-6779.

Sincerely,

Steven Galson, M.D., M.P.H.
Acting Director
Center for Drug Evaluation and Research
Food and Drug Administration

ATA Continues Dialog With FDA on Levothyroxine Dose Precision and Bioequivalence Standards

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