AMERICAN
THYROID
ASSOCIATION
FOUNDED 1923

Headquarters Office
American Thyroid Association
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October 28, 2003

Dockets Management Branch, HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

To whom it may concern:

Please add the attached letter to the docket 2003P-0387

Sincerely,

Barbara R. Smith, CAE
Executive Director

2003P-0387 C1

Docket 2003P-0387

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October 1, 2003

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Janet Woodcock, M.D.
Director, Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane, HFD-240
Rockville, MD 20857

Dear Dr. Woodcock:

I am writing on behalf of Dr. Peter Singer, Immediate Past President of the American Thyroid Association; Dr. E. Chester Ridgway, President of the Endocrine Society; and Dr. Donald Bergman, President of the American Association of Clinical Endocrinologists. We thank you for the thoughtful manner in which you and your staff recently listened to the concerns of our societies, physician members, and patients regarding dose precision and bioequivalence standards for levothyroxine sodium formulations.

We are heartened by the commitment that you made to plan and hold a workshop of sufficient depth and duration to address all of the relevant issues: bioequivalence testing baseline correction, optimal test subjects, and acceptable confidence limits; and TSH as a pharmacodynamic measure. We also support your interest in designing a crossover chronic thyroxine therapy trial with serum TSH as an outcome. We agree with you that a properly designed and executed study could address the fundamental concerns that physicians and their patients have about optimizing the safety and effectiveness of thyroxine therapy. We offer our assistance in designing, implementing, and interpreting the results of such a study.

Because of the concerns that we all share regarding thyroxine dose precision and limitations in the current bioequivalence standard, we ask that 1) FDA suspend approval of new formulations until these matters are resolved, and 2) FDA not make a final decision regarding equivalence testing until it has received further input from experts at the workshop that you proposed.

As you requested, we will send to you a draft agenda and list of potential contributors to the workshop program that you have proposed.

Although I am no longer Secretary of the American Thyroid Association, I have become president-elect and our new president, Dr. Clark Sawin, has asked me to remain the primary point of contact between the three societies and FDA. We look forward to hearing from you.

Sincerely,

Paul W. Ladenson, M.D.
President-Elect, American Thyroid Association

PWL:sr

xc: Dr. Peter Singer, Past President, American Thyroid Association
Dr. Clark Sawin, President, American Thyroid Association
Dr. Gregory Brent, Secretary, American Thyroid Association
Dr. E. Chester Ridgway, President, Endocrine Society
Dr. Donald Bergman, President, American Association of Clinical Endocrinologists
Ms. Barbara Smith, Executive Director, American Thyroid Association
Mr. Scott Hunt, Executive Director, Endocrine Society
Mr. Donald Jones, Executive Director, American Association of Clinical Endocrinologists