DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUN 8 2001

Stuart M. Pape
Patton Boggs LLP
2550 M Street N.W.
Washington, D.C. 20037-1350

Dear Mr. Pape:

This is in regard to your May 11, 2001 letter requesting that the Food and Drug Administration immediately withdraw Synthroid® from the market. We are considering the issues you raised in your letter and will respond as soon as we can. You made a statement, however, in footnote 7 that you attributed to me that I felt warrants an immediate response.

You suggested that I told one of your colleagues that FDA would withdraw from the market any levothyroxine sodium drug product that has not obtained NDA approval as of August 14, 2001. There was apparently a misunderstanding about what I said. The August 14, 1997, Federal Register notice (62 FR 43535) declaring levothyroxine sodium products to be new drugs stated that after August 14, 2000, (later extended to August 14, 2001, 65 FR 24488) any orally administered drug product containing levothyroxine sodium marketed without an approved application will be subject to regulatory action. The agency has not yet determined what action it will take with regard to any marketed levothyroxine sodium drug product that has not obtained NDA approval as of August 14, 2001. We are in the process of determining what, if any, action we will take and intend to make a public statement about how we intend to exercise our enforcement discretion as soon as we can but, in any event, in advance of the August 14, 2001 deadline. I hope this corrects any misunderstanding about my position.

Sincerely,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research