

# HOGAN & HARTSON

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April 28, 2004

## *BY HAND DELIVERY*

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

**Re: Docket No. 03P-0387  
Notice of Intent to Respond to Comments**

Dear Sir or Madam:

We are writing on behalf of Abbott Laboratories ("Abbott") regarding several recent developments related to the above-referenced Citizen Petition (the "Petition"). These developments, described below, raise substantive and technical issues that bear directly on the Petition. By this letter, we are providing notice of Abbott's intent to respond on or before June 4, 2004.

First, on April 14, 2004, Frederic J. Cohen, M.D., submitted comments on each of the major clinical and pharmacokinetic issues raised by Abbott. Dr. Cohen submitted his comments to the Petition on behalf of an unnamed pharmaceutical company with an apparent and direct interest in this matter. The Food and Drug Administration ("FDA") was unable to provide us with a copy of the comments until April 27, 2004. After reviewing the comments, we believe they bear directly on the arguments raised in the Petition and that Abbott should be provided a reasonable opportunity to respond.

Second, we recently obtained an expedited transcript of the April 14, 2004, meeting of the Advisory Committee for Pharmaceutical Science ("ACPS") on the bioequivalence of highly variable drugs. The scheduling of this meeting and the scientific and clinical issues raised there strongly support the arguments in the Petition. We intend to supplement the record in support of the Petition with excerpts from, and analysis of, this ACPS meeting.

**03P-0387**

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Dockets Management Branch

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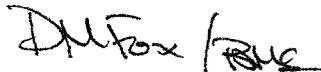
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Finally, on March 31, 2004, Jerome Stevens Pharmaceuticals submitted an amended Citizen Petition that discusses their efforts to obtain an "AB" therapeutic equivalence rating to Abbott's Synthroid. See Docket No. 04P-0061. This Citizen Petition likewise requires a response.

As discussed in FDA's May 15, 2003, letter from Jane Axelrad to Douglas Sporn, the agency invited Abbott to initiate this Citizen Petition process in order to, among other things, "provide Abbott the opportunity to comment publicly on the views and opinions of others . . . ." We welcome this opportunity and, as noted above, intend to submit our response on or before June 4, 2004.

As always, we appreciate your time and courtesy in this matter.

Sincerely,



David M. Fox  
Brian R. McCormick  
Hogan & Hartson LLP

cc: John M. Leonard, M.D.  
Douglas L. Sporn  
Neal B. Parker  
Abbott Laboratories

Kevin M. Fain  
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FDA Docket No. 03P-0126