

HOGAN & HARTSON

L.L.P.

DAVID M. FOX
PARTNER
(202) 637-5678
DMFOX@HHLAW.COM

COLUMBIA SQUARE
555 THIRTEENTH STREET, NW
WASHINGTON, DC 20004-1109
TEL (202) 637-5600
FAX (202) 637-5910
WWW.HHLAW.COM

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BY HAND DELIVERY

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

Re: **Docket No. 03P-0387**
Supplement to Citizen Petition

Dear Sir or Madam:

On behalf of Abbott Laboratories ("Abbott"), we submit the following supplement under 21 CFR 10.30(g) to the above-referenced Citizen Petition, submitted on August 25, 2003 (the "Petition"). The purpose of this submission is to place into the record a declaration by Ronald J. Sawchuk, Ph.D., Professor of Pharmaceutics and Director of Bioanalytical and Pharmacokinetic Services in the College of Pharmacy at the University of Minnesota (Tab A).

This declaration supports the pharmacokinetic issues raised by Abbott. See Petition at 8-13, 19-22, 28-38. Among other things, Dr. Sawchuk confirms the validity of the design of Abbott's Study M02-417, including its use of 450 and 400 mcg doses of levothyroxine sodium ("levothyroxine"). Dr. Sawchuk states that each of the three doses used was several times the normal dose of levothyroxine, and that each produced significant and measurable serum levothyroxine concentrations.

Dr. Sawchuk concludes that Study M02-417 demonstrates that the Food and Drug Administration's ("FDA's") recommended bioequivalence methodology, with baseline correction, is insufficiently sensitive to distinguish between levothyroxine products that differ by 12.5 percent. As discussed in the Petition and in the clinical declarations previously submitted to FDA, such

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differences in the dose of levothyroxine are clinically significant. *See* Petition at 3-4, 23-27; Petition Supplement, Docket No. 03P-0387 (Feb. 9, 2004).

As always, we appreciate your attention to this matter.

Sincerely,



David M. Fox
Katlin E. McKelvie
Hogan & Hartson L.L.P.

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

Kevin M. Fain
Office of the Chief Counsel, GCF-1

FDA Docket No. 03P-0126