

VENABLE, BAETJER, HOWARD & CIVILETTI, LLP
Including professional corporations

1201 New York Avenue, N.W., Suite 1000
Washington, D.C. 20005-3917
(202) 962-4800, Fax (202) 962-8300
www.venable.com

OFFICES IN

WASHINGTON, D.C.
MARYLAND
VIRGINIA

VENABLE
ATTORNEYS AT LAW

2629 '03 MAY 19 P1:27
May 14, 2003
David G. Adams
(202) 216-8014
dgadams@venable.com

VIA U.S. MAIL

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

Re: Docket Number 76n-0377: Notice of Participation and Request for Hearing

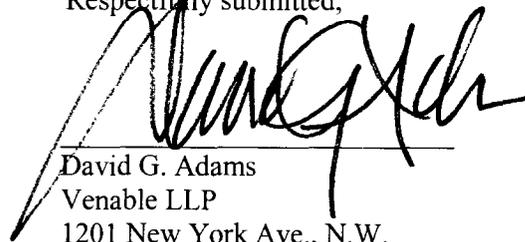
Dear Sir or Madam:

FDA published in the Federal Register of April 14, 2003, a notice providing an opportunity for a hearing in the above-referenced matter on whether there is substantial evidence of effectiveness of esterified estrogens and methyltestosterone for moderate to severe vasomotor symptoms associated with the menopause in those patients not improved by estrogen alone and on other related issues.

Pursuant to 21 C.F.R. 314.200(c)(1), Syntho Pharmaceutical, Inc., (Syntho) submits this notice of participation and request for hearing (with three copies of same) in the above-referenced matter. Syntho is an interested party because it manufactures products containing esterified estrogens and methyltestosterone that are labeled for use in treating moderate to severe vasomotor symptoms associated with the menopause in those patients not improved by estrogen alone.

Syntho will submit studies, analyses, and other information supporting its request for hearing, pursuant to 21 C.F.R. 314.200(c)(2), on or before June 13, 2003.

Respectfully submitted,



David G. Adams
Venable LLP
1201 New York Ave., N.W.
Washington, D.C. 20005
(202) 216-8014

Counsel for Syntho Pharmaceutical, Inc.
230 Sherwood Ave.
Farmingdale, New York 11735.

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