MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: August 8, 2002

FROM: Michael F. Skelly, Ph.D.
Pharmacologist

THROUGH: C. T. Viswanathan, Ph.D. CTV Aug 8, 02
Associate Director - Bioequivalence
Division of Scientific Investigations (HFD-48)

SUBJECT: Review of EIRs Covering Docket 02P-0029/CP1, a Citizen Petition concerning Climara® TD (estradiol transdermal), sponsored by Berlex/3M

TO: Dale P. Conner, Pharm.D.
Director
Division of Bioequivalence (HFD-650)

At the request of HFD-650, the Division of Scientific Investigations conducted audits of the clinical and analytical portions of the following bioequivalence study.

> Protocol #304100: "Bioequivalence comparison of 17β-estradiol, estrone, and estrone sulfate from generic transdermal estradiol system and from a modified 3M transdermal system with that from Climara transdermal estradiol system for 0.1 mg/day patches applied over 7 days"

The clinical portion of the study was conducted at Bio-Kinetic Clinical Applications, Inc., in Springfield, MO. The analytical portion of the study was conducted at AAI Deutschland GmbH & Co., in Neu Ulm, Germany.

Following the inspections at Bio-Kinetic Clinical Applications (4/30-5/1/02) and AAI (4/29-5/3/02), no Form FDA-483 was issued. There were no objectionable findings from either inspection.

Conclusions:

Following the above audits, the Division of Scientific Investigations recommends that the study data from Protocol #304100 be accepted for review.

02P-0029 M 1

After you have reviewed this transmittal memo, please append it to the original Citizen Petition.

Michael F. Skelly, Ph.D.

Final Classifications:
NAI - Bio-Kinetic Clinical Applications, Springfield, MO
NAI - AAI Deutschland, Neu Ulm, Germany