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*APPLICATION NUMBER:*

**21-674**

**PHARMACOLOGY REVIEW**

# Memo

To: NDA 21-674 8/8/03

From: Karen Davis-Bruno; Ph.D.; Supervisory Pharmacologist, HFD-510

Re: Pharmacology/Toxicology evaluation of NDA

Date: 9/2/03

NDA 21-674 (Menostar) is indicated for the prevention of post-menopausal osteoporosis. It is an ultra low dose of estradiol delivered in a transdermal patch at 0.014 mg/day estradiol. The parent NDA 20-375 (Climara) has been previously approved and delivers even higher doses of estradiol. The requisite pharmacology/toxicology data has been reviewed previously in NDA 20-375 in HFD-580 (see reviews). Since this product is estradiol, supporting nonclinical bone quality studies would not be needed for an indication of PMO. A pharmacology/toxicology review is not needed (NN) for this NDA.

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/s/

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Karen Davis-Bruno  
9/9/03 09:03:48 AM  
PHARMACOLOGIST  
P/T review NN