



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

September 28, 2001

Gail Elbek
380 N. San Marcos Road
Santa Barbara, CA 93111

Dear Ms. Elbek:

Your petition requesting the Food and Drug Administration to allow estrogen & progestin drug information available to the public is "Misbranded" due to misleading, incorrect, & withholding most important information, was received by this office on 09/28/01. It was assigned docket number 01P-0443/CP1 and it was filed on 09/28/01. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

A handwritten signature in cursive script that reads "Helen K. Harris".

Helen K. Harris
Dockets Management Branch

01P-0443

ACK1