

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER: 020181**

**ENVIRONMENTAL ASSESSMENT AND/OR FONSI**

MEMORANDUM

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

DATE: March 3, 1997  
FROM: Steve McCort  
SUBJECT: Environmental Assessment  
TO: File for NDA 20-181

APPEARS THIS WAY  
ON ORIGINAL

In accordance with the November 14, 1995 MAPP 505.1 entitled "Interim Directive-Processing Environmental Assessment Submission", this memo is placed to the file in leu of an EA review and FONSI.

The MAPP 5015.15 stipulates that for application already in house or that are submitted within six months of the issuance of the EA guidance document, no change in division EA submission practice is necessary. Since this NDA was first submitted on April 10, 1991 a separate EA review or Fonsi is not necessary.

Also, there are no extraordinary circumstances indicating that approval of this NDA would harm the environment because all the ingredients are natural products which are expected to be metabolized and not released to the environment.

/S/  
Stephen McCort  
Project Manager, HFD-510

/S/  
Duu-Gong Wu, Ph.D.  
Chemistry Team Leader  
DNDC II, HFD-510

APPEARS THIS WAY  
ON ORIGINAL

cc:

NDA 20-181  
HFD-510/Division Files  
HFD-510/DGWu/SKoch  
HFD-510/CSO/McCort

APPEARS THIS WAY  
ON ORIGINAL