

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-487 /S-004

MEDICAL REVIEW

JAN 7 1997



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Memorandum

Date: January 7, 1997

From: Therese A. Cvetkovich, M.D. TC 1/7/97
Medical Officer, DAVDP

Subject: Medical Officer Review
S-004, NDA 20487

To: NDA 20-487
NDA 20-550

Through: Rachel E. Behrman, M.D.
Team Leader, DAVDP

This supplemental application submitted December 16, 1996 provides for changes under the Clinical Pharmacology Section (Clinical Trials: Herpes Zoster Infections). These changes are found to be acceptable upon review. A letter will be sent to the applicant indicating approval of the changes. No further regulatory action is indicated.

CC:
HFD-530/MO/TCvetkovich
HFD-530/CSO/DStaten

Appears This Way
On Original