DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-715/SCS-021

Pharmacia & Upjohn
Attn: Greg Brier
Unit: 0633-298-113
7000 Portage Road
Kalamazoo, MI 49001-0199

Dear Mr. Brier:

Please refer to your new drug application 19-715/S-021 dated February 15, 2001, received October 1, 2001 submitted under section 505(b) pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Dipentum® (olzalazine sodium) Capsules.

We acknowledge receipt of your submissions dated September 28, 2001 and February 12, 2002. The February 12, 2002 submission constituted a complete response to our August 10, 2001 action letter.

This new drug application provides for the use of Dipentum® (olzalazine sodium) Capsules for the maintenance of remission of ulcerative colitis in patients who are intolerant of sulfasalazine.
We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the submitted final printed labeling.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Betsy Scroggs, Pharm. D., Consumer Safety Officer, at (301) 827-1250.

Sincerely,

{See appended electronic signature page}

Liang Zhou, Ph.D.
Chemistry Team Leader for the
Division of Gastrointestinal and Coagulation Drug Products (HFD-180)
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Liang Zhou

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