DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

Food and Drug Administration
Rockville MD 20857

NDA 19-715/S-018

Pharmacia & Upjohn Company
Attention: Gregory A. Brier
Regulatory Affairs Manager
0633-298-113
7000 Portage Road
Kalamazoo, MI 49001

Dear Mr. Brier:

Please refer to your supplemental new drug application dated August 18, 1999, received August 19, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Dipentum (olsalazine sodium) Capsules.

We acknowledge receipt of your submission dated July 23, 2001. Your submission of July 23, 2001 constituted a complete response to our April 6, 2001 action letter.

This supplemental new drug application provides for revision of the package insert to include a Geriatric Use subsection in the PRECAUTIONS section, in accordance with 21 CFR 201.57(f)(10)(ii)(A).

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (100 count package insert submitted July 23, 2001). Accordingly, the supplemental application is approved effective on the date of this letter.

Our understanding is that Dipentum is marketed in 100 and 300 count package configurations. However, you only submitted FPL for the 100 count package insert. Note, therefore, that this approval action applies only to the 100 count insert. Please submit a separate “Changes Being Effected” supplement that provides for the revision to the Geriatric Use section of the 300 count package insert.

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 Melodi McNeil, Regulatory Health Project Manager, at (301) 827-7310.

Sincerely,

{See appended electronic signature page}

Victor F. C. Raczkowski, M.D., M.Sc.
Acting Director
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
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/

Joyce Korvick

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