CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER
20-430/S-003

Correspondence

Oliver

NDA 20-430/S-003

AUG 30 2000

Organon Inc.
Attention: Ashok K. Didolkar, Ph.D.
375 Mt. Pleasant Avenue
West Orange, New Jersey 07052

Dear Dr. Didolkar:

We acknowledge receipt of your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Orgaran® (danaparoid sodium) Injection

NDA Number: NDA 20-430

Supplement Number: S-003

Therapeutic Classification: Standard (S)

Date of Supplement: August 25, 2000

Date of Receipt: August 28, 2000

This supplement proposes the following changes: (1) in the CLINICAL PHARMACOLOGY section, the addition of a subsection titled "Special Populations", with three sub-subsections titled "Geriatrics", "Pediatrics", and "Hepatic Insufficiency"; (2) in the PRECAUTIONS section, additional information in the "Geriatric Use" subsection; and (3) in the DOSAGE AND ADMINISTRATION section, the addition of a subsection titled "Use in Geriatrics".

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on October 27, 2000 in accordance with 21 CFR 314.101(a). If the application is filed, the primary user fee goal date will be June 28, 2001 and the secondary user fee goal date will be August 28, 2001.

All communications concerning this supplemental application should be addressed as follows:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Gastrointestinal and Coagulation Drug Products, HFD-180
Attention: DOCUMENT CONTROL ROOM, 6B-24
5600 Fishers Lane
Rockville, Maryland 20857

If you have any questions, contact me at (301) 827-7457.

Sincerely, 8/30/00

/S/

Karen Oliver, RN, MSN
Regulatory Health Project Manager
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research