DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 18-841 /S-012
NDA 18-841 /S-016

G.D. Searle and Co.
Attention: Susan Tegtmeyer
Associate, Regulatory Affairs
4901 Searle Parkway
Skokie, 11, 60077

Dear Ms. Tegtmeyer:

Please refer to your supplemental new drug application (18-841/S-012) dated June 14, 1996, received June 17, 1996, and supplemental application (18-841 /S-016) dated October 8,1999, received October 12,1999 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Daypro (oxaprozin) Caplets 600 mg..

We acknowledge receipt of your submissions dated March 9, December 4, 1998 and July 24, 2001 for supplemental application 18-841 /S-012 and July 24, 2001 for supplemental application 18-841 /S-016. Your submission of July 24, 2001 constituted a complete response to our August 2, 2000 action letter.

We also acknowledge receipt of your letter dated January 25, 2002 accepting draft labeling faxed to you on January 15, 2002.

Supplemental application 18-841 /S-012 provides labeling revisions to the **CLINICAL PHARMACOLOGY Individualization of Dosage, and PRECAUTIONS** sections. Supplemental application 18-841 /S-016 provides for proposed pediatric labeling revisions in accordance with 21 CFR 314.70(b) and in response to the FDA's March 5, 1999 Pediatric Written Request.

We have completed the review of these supplemental applications, 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 agreed upon enclosed labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling.

Please submit the copies of final printed labeling (FPL) electronically to each application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 18-841/S-012, NDA 18841/S-016." Approval of these submissions by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

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 Carmen DeBellas, Chief Project Management Staff, at 301-827-2040.

Sincerely,

/See appended electronic signature page)

Lee S. Simon, M.D.
Director
Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products
Office of Drug Evaluation V
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/

Lee Simon

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