



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug  
Administration  
Rockville MD 20857

NDA 11-529/S-048

McNeil Consumer Products Company  
Attention: Paula Oliver  
Director, Regulatory Affairs  
7050 Camp Hill Road  
Fort Washington, PA 19034

Dear Ms. Oliver:

Please refer to your supplemental new drug application dated January 26, 1994, received January 27, 1994, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Parafon Forte DSC (chlorzoxazone 500 mg).

We acknowledge receipt of your submission dated May 24, 1995.

This supplemental new drug application provides for changes to **CLINICAL PHARMACOLOGY** and **WARNINGS** sections of the labeling.

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 agreed upon enclosed labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

Please submit the copies of final printed labeling (FPL) electronically 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, this submission should be designated "FPL for approved supplement NDA 11-529/S-048." Approval of this submission 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

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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

Please submit one market package of the drug product when it is available.

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, R.Ph., Chief Project Manager, 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

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/s/

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Lee Simon

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