DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-821/S-045

McNeil Consumer and Specialty Pharmaceuticals
Attention: Susan Cousounis
Assistant Director
Regulatory Development
7050 Camp Hill Road
Fort Washington, PA 19034-2299

Dear Ms. Cousounis:

Please refer to your supplemental new drug application dated April 18, 2001, received April 19, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Flexeril (cyclobenzaprine HCL) Tablets 5 mg.

We acknowledge our Approvable Letter dated February 13, 2002 and receipt of your submissions, dated August 2, 2002, October 8, 2002, January 9, 14, 28 and 30, 2003.

This supplemental new drug application provides for the use of Flexeril Tablets 5 mg for the relief of muscle spasm associated with acute, painful, musculoskeletal conditions.

We completed our review of this application as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

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

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case 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 17-821/S-045. Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division/ the Division of Anti-Inflammatory, Analgesic, and Ophthalmic Drug Products 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, MD 20857

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), 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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Nancy Halonen, Regulatory Project Manager, at (301) 827-2019.

Sincerely,

{See appended electronic signature page}

Lee S. Simon, M.D.
Director,
Division of Anti-Inflammatory, Analgesic, and Ophthalmic Drug Products, HFD-550 Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosure (attached labeling)

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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