DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 12-281/S-050
NDA 12-281/S-051
NDA 12-281/S-052

Wyeth Pharmaceuticals
Attention: Tracey Rockney
Director
Worldwide Regulatory Affairs
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Ms Rockney:

Please refer to your supplemental new drug applications dated June 18, 2001 (S-050), June 22, 2001 (S-051) August 14, 2002 (S-052), received June 19, 2001 (S-050), June 27, 2001 (S-051) and August 15, 2002, submitted under section 505 (b) of the Federal Food, Drug, and Cosmetic Act for Robaxisol (methocarbamol USP and aspirin, USP) Tablets.

Your submission of December 23, 2003 constituted a complete response to our April 3, 2003 (S-050 & S-051) and September 9, 2003 (S-052) action letters.

These supplemental new drug applications provide for multiple changes to the labeling.

We completed our review of these applications, as amended. These applications are 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 submitted labeling dated December 23, 2003.

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 15 of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 12-281/S-050, 051 and 052." Approval of these submissions by FDA is not required before the labeling is used.

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, HFD-410
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 Jane Dean, RN, Regulatory Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Brian E. Harvey, M.D., Ph.D.
Acting Division Director
Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products, HFD-550
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/

Brian Harvey
2/10/04 11:24:25 AM