DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-777

ECR Pharmaceuticals
404 Saw Mill Road
East Berne, NY 12059

Attention: Robert G. Ferraino
Regulatory Affairs

Dear Mr. Ferraino:

Please refer to your new drug application (NDA) dated April 29, 2004, received April 30, 2004, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for AMRIX (cyclobenzaprine hydrochloride) Extended-Release Capsules, 15 and 30 mg.

We acknowledge receipt of your submissions dated May 6, 7, 9, and 27, June 29, July 6, 20, 21 and 30, August 30, October 4, and December 10, 17, and 23, 2004, January 22 (3), and 29 (2), February 11, and 16, March 8 (2), April 11, May 19, June 10, and September 23, 2005, and August 5, September 19, November 22, 2006, and January 12, 23, and 25, 2007. The August 5, 2006 submission constituted a complete response to our February 28, 2005, action letter.

This new drug application provides for the use of AMRIX (cyclobenzaprine hydrochloride) Extended-Release Capsules, 15 and 30 mg for use as an adjunct to rest and physical therapy for relief of muscle spasm associated with acute, painful musculoskeletal conditions.

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

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert, patient package insert, and immediate carton and container labels. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

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 and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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

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 Lisa Malandro, Regulatory Project Manager, at (301) 796-1251.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Director
Division of Anesthesia, Analgesia
and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure