DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21777/S-006
NDA 21777/S-009

SUPPLEMENT APPROVAL

IVAX International GmbH
c/o Cephalon, Inc.
41 Moores Road
P.O. Box 4011
Frazer, PA 19355

Attention: James M. Ciciriello
Director, Regulatory Affairs

Dear Mr. Ciciriello:

Please refer to your Supplemental New Drug Application (sNDA) dated June 30, 2009, received June 30, 2009, (S-006) and sNDA submission dated April 26, 2011, received April 26, 2011, (S-009) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Amrix™ (cyclobenzaprine hydrochloride) Extended Release Capsules.

We acknowledge receipt of your amendments dated January 19, February 25, June 29, and July 12, 2011, and December 13, 2012, and January 28, April 25, May 17, and June 04, 2013. The December 13, 2012, submission constituted a complete response to our December 14, 2011, action letter.

Prior Approval supplemental new drug application (S-006) provides for the conversion of the labeling for Amirx to comply with the Physician Labeling Rule (PLR) format.

Prior Approval supplemental new drug application (S-009) provides for a new patient package insert.

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content

of labeling must be identical to the enclosed labeling (text for the package insert and text for the patient package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

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 Sadaf Nabavian, Regulatory Project Manager, at (301) 796-2777.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Division Director
Division of Pulmonary, Allergy, and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

BADRUL A CHOWDHURY
06/07/2013