CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

203340Orig1s000

OTHER ACTION LETTERS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 203340

COMPLETE RESPONSE

Arbor Pharmaceuticals
Attention: Allison Lowry
Director, Quality and Regulatory Affairs
980 Hammond Drive, Suite 1250
Atlanta, GA 30328

Dear Ms. Lowry:

Please refer to your New Drug Application (NDA) dated November 18, 2011, received November 18, 2011, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Nymalize, (nimodipine) 60 mg/ml Oral Solution.

We acknowledge receipt of your amendments dated November 21, 2011, January 10, 2012, February 10, 2012, February 17, 2012, March 5, 2012, March 27, 2012, March 30, 2012, April 19, 2012, April 30, 2012, May 4, 2012, May 7, 2012, May 9, 2012, May 18, 2012, May 25, 2012, June 22, 2012, June 29, 2012, July 16, 2012, and August 1, 2012.

We have completed our review of this application, as amended, and have determined that we cannot approve this application in its present form. We have described our reasons for this action below and, where possible, our recommendations to address these issues.

FACILITY INSPECTIONS

During a recent inspection of the Enterprises Importfab manufacturing facility for this application, our field investigator conveyed deficiencies to the representative of the facility. Satisfactory resolution of these deficiencies is required before this application may be approved.

LABELING

We reserve comment on the proposed labeling until the application is otherwise adequate. If you revise labeling, your response must include updated content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm.

OTHER

Within one year after the date of this letter, you are required to resubmit or take other actions available under 21 CFR 314.110. If you do not take one of these actions, we may consider your lack of response a request to withdraw the application under 21 CFR 314.65. You may also

request an extension of time in which to resubmit the application. A resubmission must fully address all the deficiencies listed. A partial response to this letter will not be processed as a resubmission and will not start a new review cycle.

Under 21 CFR 314.102(d), you may request a meeting or telephone conference with us to discuss what steps you need to take before the application may be approved. If you wish to have such a meeting, submit your meeting request as described in the FDA's "Guidance for Industry - Formal Meetings Between the FDA and Sponsors or Applicants," May 2009 at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM153222.pdf.

The drug product may not be legally marketed until you have been notified in writing that this application is approved.

If you have any questions, call Vandna Kishore, RPh, Regulatory Project Manager, at (301) 796-4193.

Sincerely,

{See appended electronic signature page}

Russell Katz, MD
Director
Division of Neurology Products
Office of Drug Evaluation I
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/

RUSSELL G KATZ
08/16/2012