DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22165/S-004

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT

Nautilus Neurosciences, Inc
Attention: William Maichle
Chief Executive Officer
135 Route 202/206
Bedminster, NJ 07921

Dear Mr Maichle:

Please refer to your Supplemental New Drug Applications (sNDA) dated May 13, 2011, received May 13, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Cambia (diclofenac powder for oral solution).

We acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessments dated December 17, 2010 and April 19, 2011.

This supplemental new drug application proposes to eliminate the requirement for the approved Cambia (diclofenac powder for oral solution) REMS.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Cambia (diclofenac powder for oral solution) was originally approved on June 17, 2009. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS.

You propose that FDA no longer require a REMS for Cambia (diclofenac powder for oral solution).

We have determined that maintaining the Medication Guide as part of the approved labeling is adequate to address the serious and significant public health concern and meets the standard in 21 CFR 208.1. Therefore, it is no longer necessary to include the Medication Guide as an element of the approved REMS to ensure that the benefits of Cambia (diclofenac powder for oral solution) outweigh its risks.

Therefore, we agree with your proposal and a REMS for Cambia (diclofenac powder for oral solution) is no longer required.

We remind you that the Medication Guide will continue to be part of the approved labeling in accordance with 21 CFR 208.

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 Lana Chen, PharmD, Regulatory Project Manager, at (301) 796-1056.

Sincerely,

{See appended electronic signature page}

Russell G. 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
07/20/2011