DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022377/S-002 & S-004

SUPPLEMENT APPROVAL

Meridian Medical Technologies, Inc.
Attention: Ellen Kay Losciuto
Manager, Regulatory Affairs
1945 Craig Road
St. Louis, MO 63146

Dear Ms. Losciuto:

Please refer to your Supplemental New Drug Applications (sNDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for:

NDA Number	Supplement Number	Product Name	Submission Date	Receipt Date
022377	S-002	Alsuma (sumatriptan) injection	July 10, 2012	July 12, 2012
This "Changes Being Effected" supplemental new drug application proposes:				
1. To clarify the dosing information to make it consistent with the *Dosage and Administration* section, the addition of "The maximum recommended dose that may be given in 24 hours is two doses of ALSUMA separated by at least 1 hour." to the *Contraindications* section of labeling. 2. Revised distributor information.				

We acknowledge receipt of your amendments dated July 17, 2012, November 13, 2012, July 9, 2013 and May 19, 2014.

NDA Number	Supplement Number	Product Name	Submission Date	Receipt Date
022377	S-004	Alsuma (sumatriptan) injection	June 22, 2012	June 25, 2012
This "Changes Being Effected" supplemental new drug application proposes:				
The addition of Medication Overuse Headache to the *Warnings and Precautions* section of labeling				

During a discussion period following receipt of your July 10, 2012 supplement, we requested the statement "The maximum recommended dose that may be given in 24 hours is two doses of ALSUMA separated by at least 1 hour." be removed from the *Contraindications* section of labeling. The statement has been removed as agreed upon. 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

We note that your May 19, 2014, submission includes 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.

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

Sincerely,

{See appended electronic signature page}

Eric Bastings, M. D.
Deputy Director
Office of Drug Evaluation I
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/

ERIC P BASTINGS
06/05/2014