



NDA 21-006 S-006
S-009
S-010

Endo Pharmaceuticals, Inc.
Attn: Ira Lentz, Associate Director, Regulatory Affairs
100 Endo Boulevard
Chadds Ford, PA 19317

Dear Mr. Lentz:

Please refer to the following supplemental new drug applications submitted section 505(b) of the Federal Food, Drug, and Cosmetic Act for Frova (frovatriptan succinate) Tablets 2.5 mg.

Supplement Number:	Letter Date:	Receipt Date:
S-006	June 29, 2006	June 30, 2006
This supplemental new drug application was submitted in response to an Agency letter dated May 25, 2006 and provides for revision of the WARNINGS, PRECAUTIONS; Drug Interactions section, and PRECAUTIONS; Information for Patients section of the package insert to include information concerning serotonin syndrome with concomitant use of triptans and SSRIs/SNRIs.		
S-009	March 15, 2007	March 16, 2007
This supplemental new drug application was submitted in response to an Agency letter dated December 22, 2006 and provides for revision of the ADVERSE REACTIONS section of the package insert to include reports of seizure in close temporal association with triptan use in the "Postmarketing Experience" section of the label.		
S-010	April 11, 2007	April 12, 2007
This supplemental new drug application was submitted in response to an Agency email dated December 20, 2006 and provides for additional revision of the WARNINGS, PRECAUTIONS; Drug Interactions section, and PRECAUTIONS; Information for Patients section of the package insert and to the Patient Package Insert to include information concerning serotonin syndrome with concomitant use of triptans and SSRIs/SNRIs.		

We have completed our review of supplemental new drug applications S-009 and S-010 and they are approved, effective on the date of this letter, for use as recommended in the enclosed content of labeling [21 CFR 314.50(1)], which is identical to the content of labeling in Structured Product Labeling (SPL) format submitted on April 11, 2007. To facilitate the transmission of labeling to the National Library of Medicine for public dissemination, please resubmit this content of labeling in SPL format as soon as possible, but no later than 14 days from the date of this letter. For administrative purposes, please designate this submission, "SPL for approved NDA 21-006." (or "SPL for approved supplements NDA 21-006/S-009/S-010.")

We also note that supplemental application NDA 21-006/S-006, submitted on June 26, 2006, has been superseded by application S-010. Therefore, we will not review supplemental application S-006 but will retain it in our files.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Ms. Lana Chen, Regulatory Project Manager, at (301) 796-1056.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Division Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure

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

/s/

Russell Katz

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