



NDA 19-998/S-013

Ovation Pharmaceuticals, Inc.
Attention: Tom Stothoff
Associate Director, Global Regulatory Affairs
Four Parkway North, Suite 200
Deerfield, IL 60015

Dear Mr. Stothoff:

Please refer to your supplemental new drug application dated July 29, 2005, received August 1, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Chemet[®] (succimer) Capsules.

We acknowledge receipt of your submissions dated January 19, 2007 and July 5, 2007.

Your submission of July 5, 2007 constituted a complete response to our February 1, 2006 action letter.

This supplemental new drug application provides for revisions to the Preclinical Toxicology subsection of the CLINICAL PHARMACOLOGY section.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and indicated in the enclosed labeling.

The final printed labeling (FPL) must be identical, to the enclosed labeling (text for the package insert) and/or submitted labeling (package insert submitted July 5, 2007).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 19-998/S-013.**" Approval of this submission by FDA is not required before the labeling is used.

We acknowledge your plan for communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter). We request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20852-9787

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 Hyon-Zu Lee, Pharm.D., Regulatory Project Manager, at 301-796-2050.

Sincerely,

{See appended electronic signature page}

Rafel Dwaine Rieves, M.D.
Acting Director
Division of Medical Imaging and Hematology Products
Office of Oncology Drug Products
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/

Rafel Rieves

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