



NDA 19-998/S-017

**SUPPLEMENT APPROVAL**

Lundbeck Inc.  
Attention: Kathryn Patterson  
Associate Director, Regulatory Affairs  
Four Parkway North, Suite 200  
Deerfield, IL 60015

Dear Ms. Patterson:

Please refer to your Supplemental New Drug Application (sNDA) dated September 9, 2010, received September 10, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Chemet<sup>®</sup> (succimer) Capsules.

This “Changes Being Effected” supplemental new drug application provides for a revised immediate container label.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling.

**IMMEDIATE CONTAINER LABEL**

Submit final printed container label that is identical to the enclosed immediate container label and/or immediate container label submitted on September 9, 2010, as soon as they are available, but no more than 30 days after they are printed.

Please submit the label electronically according to the guidance for industry titled “Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).” Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission “**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 19-998/S-017.**” Approval of this submission by FDA is not required before the labeling is used.

**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 Hyon-Zu Lee, Pharm.D., Regulatory Project Manager, at 301-796-2192.

Sincerely,

*{See appended electronic signature page}*

Ann Farrell, M.D.  
Director (Acting)  
Division of Hematology Products  
Office of Oncology Drug Products  
Center for Drug Evaluation and Research

ENCLOSURE(S):  
Container Labeling

---

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

---

/s/

---

ANN T FARRELL  
10/14/2010