DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-032/S-026

Ross Products Division, Abbott Laboratories
625 Cleveland Avenue
Columbus, OH 43215-1754

Attention: Elizabeth M. Zola, Pharm. D.
Associate Director, Regulatory Affairs

Dear Dr. Zola:

Please refer to your supplemental new drug application dated October 27, 2004, received October 28, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Survanta (beractant) Intratracheal Suspension.

We acknowledge receipt of your submissions dated November 15, 2004, and January 7, 2005.

This "Changes Being Effected" supplemental new drug application provides for revised labeling (package insert, vial and carton) for Survanta 4 mL and 8 mL vials, to reflect the change in manufacturer name from Abbott Laboratories to Hospira, Inc. (for Ross Products Division, Abbott Laboratories).

We have completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended with the editorial revision listed below.

> Reinstate the small box on the front panel of the vial labels, which allows the healthcare professional to record the date and time when Survanta is removed from the refrigerator.

The final printed labeling (FPL) for the package insert and carton labels must be identical to labeling submitted October 27, 2004. However, the final printed labeling for the immediate container must be identical, and include the minor editorial revisions indicated, to that submitted on October 27, 2004. These revisions are the terms of the approval of this application.

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 20-032/S-026**." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter 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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Christine Yu, R.Ph., Regulatory Project Manager, at (301) 827-1051.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Director
Division of Pulmonary and Allergy Drug Products
Office of Drug Evaluation II
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/

Badrul Chowdhury
4/28/05 04:00:46 PM