DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-032/S-036

Abbott Laboratories
3300 Seltzer Road
Columbus, OH 43219-3034

Attention: Elizabeth Zola
Associate Director, Regulatory Affairs

Dear Ms. Elizabeth Zola:

Please refer to your supplemental new drug application dated December 10, 2008, received December 12, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Survanta (beractant) intratracheal suspension.

This "Changes Being Effected" supplemental new drug application provides for an administrative name change of manufacturer from Hospira to Abbott.

We have 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.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for package insert and patient instructions for use) submitted December 10, 2008. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 20-032/S-036.

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
Food and Drug Administration
Suite 12B05
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 Angela Robinson, Senior Regulatory Project Manager Regulatory Project Manager, at (301) 796-2284.

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

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