DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-744/S-019

Dey, L.P.
2751 Napa Valley Corporation Drive
Napa, CA 945588

Dear Michelle Carpenter:

Please refer to your supplemental new drug application dated April 17, 2008, received April 18, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Curosurf (poractant alpha) intratracheal suspension.

This "Changes Being Effected" supplemental new drug application provides for revision of the package insert (PI) to include the addition of "pulmonary hemorrhage" to the adverse events 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.

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, 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

Enclosure Approved Labeling

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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