DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-744/S-002

Dey L.P.
1571 Napa Valley Corporate Drive
Napa, CA 94558

Attention: Gabe Lebovic, Ph.D.
Director of Regulatory Affairs, CMC and Toxicology

Dear Dr. Lebovic:

Please refer to your supplemental new drug application dated October 2, 2000, received October 3, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Curosurf (poractant alfa) Intratracheal Suspension.

We acknowledge receipt of your submissions dated July 17 and November 21, 2002, and October 16, 2003. Your submission of October 16, 2003, constituted a complete response to our November 19, 2002, action letter.

This supplemental new drug application proposes changes in how the active ingredients in the drug product are described in the DESCRIPTION and HOW SUPPLIED sections of package insert, supported by recent release and stability data.

We have completed our review of this application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the submitted labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert text submitted October 16, 2003). We note that you plan to revise the composition section of the carton labels to correspond with the changes approved in this supplement.

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-744/S-002." Approval of the 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 Ms. Christine Yu, R.Ph., Regulatory Project Manager, at (301) 827-1051.

Sincerely,

{See appended electronic signature page}

Richard Lostritto, Ph.D.
Chemistry Team Leader
Division of Pulmonary and Allergy Drug Products, HFD-570
DNDC II, Office of New Drug Chemistry
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/

Richard Lostritto

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