DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-744

NOV 18 1999

Dey Laboratories
271 Napa Valley Corporate Drive
Napa, California 94558

Attention: Peggy J. Berry
Director, Regulatory Affairs

Dear Ms. Berry:

Please refer to your new drug application (NDA) dated July 3, 1996, received July 3, 1996, 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 August 7, 9, 16, 29, and 30, September 4 and 10, October 4, November 1 and 8, and December 5, 10, 13, 16, and 20, 1996, January 16, February 18, 20 and 26, March 21 and 27, April 14 and 25, May 13, 19, and 21, June 2, July 3, and September 8, 1997, March 3 and 19, April 7 and 21, May 15, July 13 and 28, and November 18, 1998, and May 14, July 2 and 15, August 16, October 6, 15, 19, 21, 25 and 26, and November 5, 8, 15, and 18, 1999. Your submission of May 14, 1999, constituted a complete response to our September 3, 1998, action letter.

This new drug application provides for the use of Curosurf (poractant alfa) Intratracheal Suspension for the treatment (rescue) of Respiratory Distress Syndrome (RDS) in premature infants.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted November 18, 1999, immediate container and carton labels submitted November 15, 1999) with the following editorial changes.

1. On the back panel of the carton label, delete the sentence that states "DO NOT remove from refrigerator for more than 24 hours" and replace it with the following sentence, "Unopened vials of CUROSURF may be warmed to room temperature for up to 24 hours prior to use."

2. On the back panel of the carton label, revise the last sentence to read "DO NOT warm to room temperature and return to refrigerated storage more than once."

3. On the front panel of the 3-mL carton label, revise the last statement to read "Carton contains one 3 mL vial."

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 20-744." Approval of this submission by FDA is not required before the labeling is used.

We remind you of the Phase 4 commitment specified in your October 15, 1999, submission. You committed to further evaluating the [redacted] method currently in use to determine

Final report/supplement submission: A summary of these evaluations, together with their supporting data, will be submitted to this NDA within six months of the date of this letter. If a method, either visual or instrumental, with improved discrimination is found, it will be submitted in a prior-approval supplement along with its supporting method validation and updated specification sheets for the drug substance and drug product. For administrative purposes, all submissions relating to this Phase 4 commitment should be clearly labeled "**PHASE 4 COMMITMENT**."

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Mr. Keary Dunn, Regulatory Project Manager, at (301) 827-5580.

Sincerely,

John K. Jenkins, M.D., F.C.C.P.
Director
Office of Drug Evaluation II
Center for Drug Evaluation and Research