NDA 20-521

ONY, Inc.
1576 Sweet Home Road
Amherst, New York 14228

Attention: Edmund A. Egan, M.D.
President

Dear Dr. Egan:

Please refer to your new drug application (NDA) dated July 25, 1995, received July 31, 1995, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Infasurf (calfactant) Intratracheal Suspension.

We acknowledge receipt of your submissions dated March 13, June 30, July 13, August 4, 10, 21, and 22, September 21 and 26, October 16, November 3, 6, and 8, and December 1, 4, and 15, 1995; January 23, February 9 and 20, March 6, April 12, May 10 and 24, July 11 and 19, August 6 and 13, September 26, November 6, 14, and 22, and December 9 and 24, 1996; February 12, March 14, April 7, 9, 21, 22, 24, and 29, May 2, 5, and 6, October 22, and December 19 and 23, 1997; and February 16, March 10, April 8, 10, 15, and 27, May 15, and June 11, 1998. Your submission of February 16, 1998, constituted a full response to our May 7, 1997, action letter. The user fee goal date for this application is August 16, 1998.

This new drug application provides for the use of Infasurf (calfactant) Intratracheal Suspension for the prevention and treatment of Respiratory Distress Syndrome (RDS) in neonates.

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 enclosed labeling text. Accordingly, the application is approved effective on the date of this letter.

This approval is specifically limited to drug product manufactured from drug substance prepared using the n(b)(4)TS----------ocess described in the original application. Drug product produced from drug substance manufactured with any other process (e(b)(4)CC----------ay not legally be marketed until a supplemental application describing and validating the new process has been submitted and approved. We encourage you to consult the Division of Pulmonary Drug Products with regard to the data required to support approval of such a change in the manufacturing process prior to submission of a supplemental application.

The final printed labeling (FPL) must be identical to the enclosed marked-up draft labeling (text for the package insert) and submitted draft labeling (immediate container and carton labels dated June 11, 1998). Our changes in the text are noted by an asterisk in the left column. 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 20-521." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your Phase 4 commitments specified in your submission dated June 11, 1998. These commitments, along with completion dates agreed upon, are listed below.

(b)(4)CC----------

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We remind you of the agreement that the currently approved expiry periods of 12 months for the drug substance and 12 months for the drug product manufactured from it, are based on the completion of your commitments listed above. These expiry periods can be extended only through prior-approval supplements with additional supportive studies.

Submit protocols to this NDA as correspondence. In addition, under 21 CFR 314.82(b)(2)(vii), we request that you include a status summary of each commitment in your annual report to this NDA. For administrative purposes, all submissions relating to these Phase 4 commitments must be clearly designated “Phase 4 Commitments.”

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 Dr. Denise Toyer, Project Manager, at (301) 827-5584.

Sincerely,

James Bilstad, M.D.
Director
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure