DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-521/S-008

ONY, Inc.
Baird Research Park
1576 Sweet Home Road
Amherst , NY 14228

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

Dear Dr. Egan:

Please refer to your supplemental new drug application dated September 5, 2001, received September 6, 2001, 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 December 3, 2001, and January 10, August 9, and December 12, 2002.

Your submission of August 9, 2002, constituted a complete response to our January 4, 2002, action letter.

This supplemental new drug application provides for the addition of a 3 ml drug product presentation to the market, i.e., the same container closure but smaller fill, and for the changing of the pH acceptance criteria for both the 3 ml and 6 ml vial presentations from 5.0 - 6.0 to 5.0 - 6.2.

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 and the agreed upon minor editorial revisions listed below.

The following labeling revisions listed below will be implemented before marketing the 3 mL presentation and submitted in the next annual report.

a. In the DESCRIPTION section of the package insert, "It has a pH 5.0-6.0" will be changed to "It has a pH 5.0-6.2 (target pH 5.7)."

b. The carton labels will contain the pH statement in the same format as in the package insert.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted labeling (package insert, immediate container and carton labels submitted August 9, 2002). These revisions are terms of the approval of this application.

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 ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-521/S-008" Approval of this submission by FDA is not required before the labeling is used.

We remind you of your agreement to implement the following before marketing the 3 mL presentation, as stated in your submission dated December 12, 2002.

> Revise drug product specifications to include new pH acceptance criteria and target pH. Include footnote stating that these are interim specifications and will be re-examined in a prior approval supplement to be submitted by September 15, 2003.

We also remind you of your postmarketing study commitment in your submission dated December 12, 2002. This commitment is listed below.

> ONY commits to conduct a study to investigate the source of pH increase observed after the manufacturing (sterilization) and storage of the drug product and saline in the current container closure. This study will include the investigation of possible changes to the following:
>
> a. Material and cleaning/pre-extraction procedures of vial.
> b. Material and cleaning/pre-extraction procedures of stoppers.
> c. Current manufacturing process, e.g., prolonging/modification of the sterilization cycle for the container closure components.
>
> ONY will submit the proposed changes to the container closure and/or the manufacturing process, as well as the resulting changes in pH specifications, identified by this study, in a prior approval supplement to this NDA by September 15, 2003.

In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "Postmarketing Study Protocol", "Postmarketing Study Final Report", or "Postmarketing Study Correspondence."

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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

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}

Guirag Poochikian, 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/

Guiragos Poochikian

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