

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

021746Orig1s000

Trade Name: Surfaxin Intratracheal Suspension.

Generic Name: lucinactant

Sponsor: Discovery Laboratories

Approval Date: March 6, 2012

Indications: for the prevention of respiratory distress syndrome in premature infants

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APPLICATION NUMBER:

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APPROVAL LETTER



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-746

NDA APPROVAL

Discovery Laboratories
2600 Kelly Road, Suite 100
Warrington, PA 18976-3622

Attention: Russell G. Clayton, Sr., D.O.
Vice President, Academic and Medical Affairs

Dear Dr. Clayton:

Please refer to your New Drug Application (NDA) dated and received April 13, 2004, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Surfaxin (lucinactant) Intratracheal Suspension.

We acknowledge receipt of your amendments dated September 2, 7, and 21, October 5 and 10, and November 11 and 14, 2011, and January 16, 19, and 23, February 8, 13, 16, 23, 27, and 29, and March 1, 2012.

The September 2, 2011, submission constituted a complete response to our April 17, 2009, action letter.

This new drug application provides for the use of Surfaxin (lucinactant) Intratracheal Suspension for the prevention of respiratory distress syndrome in premature infants.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling text for the package insert. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE-CONTAINER LABELS

Submit final printed carton and container labels that are identical to the carton and immediate-container labels submitted on February 17, 2012, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled “Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).” Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission “**Final Printed Carton and Container Labels for approved NDA 21-746**” Approval of this submission by FDA is not required before the labeling is used.

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

ADVISORY COMMITTEE REVIEW

Your application for lucinactant was not referred to an FDA advisory committee because outside expertise was not necessary; there were no controversial issues that would benefit from advisory committee discussion.

EXPIRY DATING PERIOD

The approved shelf life for the product is 12 months when stored under the recommended storage conditions as indicated in the label: Store SURFAXIN in a refrigerator at 2° to 8°C (36° to 46°F). Due to the observed instability of the drug product, we recommend that you extend the shelf life only via a prior approval supplement.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indications in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because this drug product for this indication has an orphan drug designation, you are exempt from this requirement.

POSTMARKETING COMMITMENTS NOT SUBJECT TO THE REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitment in your submission dated March 2, 2012.

PMC # 1879-1: You commit to transfer responsibility from Discovery Laboratories, Warrington, Pennsylvania, to (b) (4) for quality assurance (QA) and data analysis of the analytical method for testing the biological activity of the drug product (Method DP-032). Your final study report to support transfer of responsibility should be submitted as a Prior Approval Supplement (PAS). Your PAS should include a statement that the analytical facility at (b) (4) is ready for inspection and is qualified to assume full responsibility for all functions related to Method DP-032, consistent with current good manufacturing practices (CGMPs), including data QA and analysis. The transfer of responsibilities from Discovery to (b) (4) will occur upon the review and approval of the PAS by the Agency.

Final Report Submission: January 30, 2014

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

MEDWATCH-TO-MANUFACTURER PROGRAM

The MedWatch-to-Manufacturer Program provides manufacturers with copies of serious adverse event reports that are received directly by the FDA. New molecular entities and important new biologics qualify for inclusion for three years after approval. Your firm is eligible to receive copies of reports for this product. To participate in the program, please see the enrollment instructions and program description details at <http://www.fda.gov/Safety/MedWatch/HowToReport/ucm166910.htm>.

POST-ACTION FEEDBACK MEETING

New molecular entities and new biologics qualify for a post-action feedback meeting. Such meetings are used to discuss the quality of the application and to evaluate the communication process during drug development and marketing application review. The purpose is to learn from successful aspects of the review process and to identify areas that could benefit from improvement. If you would like to have such a meeting with us, call the Project Coordinator for this application.

If you have any questions, call Angela Ramsey, Project Coordinator, at (301) 796-2284.

Sincerely,

{See appended electronic signature page}

Curtis J. Rosebraugh, M.D., M.P.H.
Director
Office of Drug Evaluation II
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

Content of Labeling
Carton and Container Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

CURTIS J ROSEBRAUGH
03/06/2012