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RESEARCH**

*APPLICATION NUMBER:*

**21-648**

**APPROVAL LETTER**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 21-648

Roxane Laboratories, Inc.  
Attention: Ms. Elizabeth Ernst  
1809 Wilson Rd.  
Columbus, Ohio 43228

Dear Ms. Ernst:

Please refer to your new drug application (NDA) dated April 10, 2003, received April 25, 2003 (user fee receipt date), submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Digoxin 0.05 mg/mL Elixir USP.

We acknowledge receipt of your submissions dated March 4, 10, 22, and 25, April 2, June 16, 17, and 25, July 7 and 28, and August 24, 2004. Your submissions of June 25 and July 28, 2004 constituted a complete response to our February 25, 2004 approvable letter.

This new drug application provides for the use of Digoxin 0.05 mg/mL Elixir for the treatment of heart failure and atrial fibrillation.

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 submitted final printed labeling (package insert, carton and container labels) included in your submission dated June 25, 2004.

If you choose to use a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. You should submit any proprietary name to the Agency for our review prior to its implementation.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for this application.

In addition, please 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 the Division of Cardio-Renal Drug Products and two copies of both the promotional materials and the package inserts directly to:

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

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We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

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, please contact:

Mr. Edward Fromm  
Regulatory Health Project Manager  
(301) 594-5332

Sincerely,

*{See appended electronic signature page}*

Norman Stockbridge, M.D., Ph.D.  
Acting Director  
Division of Cardio-Renal Drug Products  
Office of Drug Evaluation I  
Center for Drug Evaluation and Research

Enclosure: Final Printed Labeling

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/s/

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Norman Stockbridge  
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