

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*  
**75-175**

**CORRESPONDENCE**

BIOEQUIVALENCY COMMENTS TO BE PROVIDED TO THE APPLICANT

ANDA: 75-175

APPLICANT: Roxane Laboratories, Inc.

DRUG PRODUCT: Cromolyn Sodium Inhalation USP, 20 mg/2mL

The Division of Bioequivalence has completed its review and has no further questions at this time.

Please note that the bioequivalency comments provided in this communication are preliminary. These comments are subject to revision after review of the entire application, upon consideration of the chemistry, manufacturing and controls, microbiology, labeling, or other scientific or regulatory issues. Please be advised that these reviews may result in the need for additional bioequivalency information and/or studies, or may result in a conclusion that the proposed formulation is not approvable.

Sincerely yours,

Dale P. ~~Cover~~ /S/, Pharm.D.  
Director  
Division of Bioequivalence  
Office of Generic Drugs  
Center for Drug Evaluation and Research



Boehringer Ingelheim  
Roxane Laboratories

Roxane Laboratories, Inc.

NEW CORREL NC 20 FAX  
~~NEW CORREL~~

Mr. Douglas Sporn  
OGD, CDER, FDA  
Metro Park North II  
7500 Standish Place, Room 150  
Rockville, MD 20855-2773

August 12, 1999

**Attention: Joseph M. Bucciné, Project Manager (301-827-5848)**

**Subject: ANDA 75-175  
Cromolyn Sodium Inhalation Solution USP, 20 mg/2 mL**

**FACSIMILE AMENDMENT  
Response to Chemistry and Labeling Comments**

Jonathan Dohnalek  
Telephone (614)241-4132  
Telefax (614)276-0321  
E-Mail jdohnalek@dpl.boehringer-  
ingelheim.com

1809 Wilson Road  
Columbus, Ohio 43228  
Telephone (614) 276-4000  
Telefax (614) 274-0974

Dear Mr. Sporn:

We wish to amend ANDA 75-175. Enclosed please find a point-by-point response to the questions in the facsimile deficiency letter dated July 30, 1999.

We have also submitted a copy of this amendment to Ms. Deborah Grelle (Pre-Approval Manager, FDA District Office, 6751 Steger Drive, Cincinnati, Ohio 45237-3097).

I can be reached by telephone at 614/241-4131 and by telefax at 614/276-0321. In my absence do not hesitate to contact my colleague, Jonathan Dohnalek, at 614/241-4132.

Respectfully,

*J. Dohnalek for*

Sean Alan F.X. Reade, M.A.  
Director, DRA - New Drugs & Services  
Roxane Laboratories, Inc.





Boehringer Ingelheim  
Roxane Laboratories

Mr. Douglas Sporn  
OGD, CDER, FDA  
Metro Park North II  
7500 Standish Place, Room 150  
Rockville, MD 20855-2773

Roxane Laboratories,  
Inc.

**NDA ORIG AMENDMENT**

*N/AC*

February 22, 1999

**Attention: Lt. Denise Huie, Project Manager (301-827-5848)**

**Subject: ANDA 75-175  
Cromolyn Sodium Inhalation Solution USP, 20 mg/2 mL**

**MAJOR AMENDMENT  
Chemistry/Labeling Deficiencies**

Jonathan Dohnalek  
Telephone (614) 241-4132  
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E-Mail  
jdohnalek@col.boehringer-  
ingelheim.com

1809 Wilson Road  
Columbus, Ohio 43228  
Telephone (614) 276-4000  
Telefax (614) 274-0974

Dear Mr. Sporn:

We wish to amend ANDA 75-175. Enclosed please find a point-by-point response to the questions in the deficiency letter dated February 10, 1998.

We have also submitted a copy of this amendment to Ms. Deborah Grelle (Pre-Approval Manager, FDA District Office, 6751 Steger Drive, Cincinnati, Ohio 45237-3097).

I can be reached by telephone at 614/241-4131 and by telefax at 614/276-0321. In my absence do not hesitate to contact my colleague, Jonathan Dohnalek, at 614/241-4132.

Respectfully,

*J. Dohnalek for Sean Alan Reade*

Sean Alan F.X. Reade, M.A.  
Director, DRA - New Drugs & Services  
Roxane Laboratories, Inc.

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**FEB 23 1999**

**GENERIC DRUGS**

July 25, 1997

Office of Generic Drugs  
Center for Drug Evaluation and Research  
Food and Drug Administration  
Metro Park North II  
7500 Standish Place, Room 150  
Rockville, MD 20855

**Re: Cromolyn Sodium Inhalation Solution USP, 20 mg/2 mL**

**ORIGINAL SUBMISSION**

Dear Sir or Madame:

Under the provisions of 21 CFR 314.94, Roxane Laboratories, Inc. herewith submits an abbreviated new drug application for Cromolyn Sodium Inhalation Solution USP, 20 mg/2 mL. The active ingredient in this product is Cromolyn Sodium USP.

This ANDA is formatted in accordance with the Guidance for Industry, Organization of an Abbreviated New Drug Application and an Abbreviated Antibiotic Application, issued April 1997.

The product will be tested according to the enclosed specifications and will be labeled and marketed as Cromolyn Sodium Inhalation Solution USP, 20 mg/2 mL. Draft labeling is contained in Section V of this application. Samples will be submitted upon assignment of the ANDA number and at the Office's request and direction. The reference listed product is INTAL® Nebulizer Solution (cromolyn sodium inhalation solution, USP), 20 mg/2 mL unit dose ampule, manufactured by Rhône-Poulenc Rorer, marketed by Fisons Pharmaceuticals. A request for a waiver of *in vivo* bioequivalence study requirements is contained in Section VI of this application.

As explained in Sections IX and X, the product will be manufactured, packaged, labeled and tested by Roxane Laboratories, Inc. No contract manufacturers or packagers are used.

Three copies of the methods validation package (Section XXII) are contained in separate volumes under this cover letter.

If you have any comments or questions, please contact me at the telephone number listed below. Thank you.

Sincerely,



Sean Alan F. X. Reade, M.A.  
Director of Regulatory Affairs  
Roxane Laboratories, Inc.  
614/276-4000, ext. 2345  
FAX: 614/276-0321

Enclosure

ROXANE • PAIN • INSTITUTE



...touching cancer and aids patients through their caregivers.  
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JUL 28 1997

GENERIC DRUGS