



NDA 21-256

ChiRhoClin, Inc.  
Attention: Edward D. Purich, Ph.D.  
Chief Executive Officer  
4000 Blackburn Lane, Suite 270  
Burtonsville, MD 20866-6129

Dear Dr. Purich:

Please refer to your new drug application (NDA) dated June 14, 2001, received June 14, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Human Secretin for Injection, a synthetic lyophilized sterile powder.

We acknowledge receipt of your submissions dated November 30, 2001, December 3, 2001, October 10, 2003, December 15, 2003, March 2, 2004, March 15, 2004, March 17, 2004, March 30, 2004, April 6, 2004, and April 7, 2004. The October 10, 2003 submission constituted a complete response to our December 14, 2001 action letter.

This new drug application provides for the use of Human Secretin for Injection for:

1. Stimulation of pancreatic secretions, including bicarbonate, to aid in the diagnosis of pancreatic exocrine dysfunction,
2. Stimulation of gastrin secretion to aid in the diagnosis of gastrinoma, and
3. Stimulation of pancreatic secretions to facilitate the identification of the ampulla of Vater and accessory papilla during endoscopic retrograde cholangiopancreatography (ERCP).

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

The final printed labeling (FPL) must be identical to, except for including the revisions indicated, the enclosed labeling (text for the package insert, immediate container and carton labels). These revisions are terms of the NDA approval. Marketing the product before making the revisions, exactly as stated, in the product's labeling may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission “**FPL for approved NDA 21-256.**” Approval of this submission by FDA is not required before the labeling is used.

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. We recommend that you 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 are waiving the pediatric study requirement for this application.

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

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

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 [www.fda.gov/medwatch/report/mmp.htm](http://www.fda.gov/medwatch/report/mmp.htm).

If you have any questions, call Ryan Barraco, Consumer Safety Officer, at 301-443-8017.

Sincerely,

*{See appended electronic signature page}*

Julie Beitz, M.D.  
Deputy Director  
Office of Drug Evaluation III  
Center for Drug Evaluation of Research

Enclosure

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Julie Beitz

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