DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-256/S-002

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

Dear Dr. Purich:

Please refer to your supplemental new drug application dated November 7, 2006, received November 9, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ChiRhoStim, (human secretin), for injection 16 and 40 mcg.

We acknowledge receipt of your submissions dated December 12, 2006, and April 4, 2007.

This supplemental new drug application provides for the following changes:

1. New formulation size (40 mcg)
2. Physicians Labeling Rule format
3. Changes to Mechanism of Action
4. Changes to Dosage and Administration

We 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 with the minor editorial revisions listed below.

1. In the package insert, Highlights of Prescribing Information, Recent Major Changes and Revision Date Sections; the date of changes should reflect the date of this approval.
2. In the package insert, Highlights of Prescribing Information, Recent Major Changes Section; it should state Dosage and Administration (2.0).

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the enclosed labeling (text for the package insert) and submitted labeling (immediate container and carton labels submitted 5/18/2007 via electronic mail to Thomas Moreno). These revisions are terms of the approval of this application.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling (text for package insert). Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

Please submit an electronic version of the FPL (immediate container and carton labels) 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 supplement NDA 21-256/S-002**." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for these products. 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:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Thomas Moreno, Regulatory Project Manager, at (301) 796-2247.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Acting Director
Division of Gastroenterology Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure (Package Insert, Vial Label, Carton Label)

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

/s/

Joyce Korvick
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