DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-136/S-006

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

Dear Dr. Purich:

Please refer to your supplemental new drug application dated August 11, 2003, received August 13, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for SecreFlo™ (synthetic secretin) Injection.

We acknowledge receipt of your submission dated December 23, 2003, which constituted a complete response to our December 12, 2003 action letter.

This supplemental new drug application provides for a change in formulation for secretin. This supplement has been administratively split from your supplemental new drug application (S-005) which provides for a change in manufacturing site. Further communication regarding S-005 will be sent to you under separate cover.

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 submitted labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted August 11, 2003).

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-136/S-006." Approval of this submission by FDA is not required before the labeling is used.

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, HFD-410
FDA
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).

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

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D., M.S.
Director
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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
3/1/04 03:55:40 PM
for Dr. Robert Justice