DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-136/S-011

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 May 9, 2005, received May 10, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for SecreFlo (secretin) for Injection.

We acknowledge receipt of your submissions dated May 25 and August 12, 2005

This supplemental application proposes the following changes:

- Replace all instances of SecreMax™ with SecreFlo™.
- Replace the SecreMax™ trademark statement with "SecreFlo™ is a registered trademark of Repligen Corporation, Waltham, MA."
- Replace all instances of ChiRhoClin logo with the Repligen Corporation logo.

We completed our review of this application and it 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, bottle and carton labels submitted May 9, 2005).

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-011. Approval of this submission by FDA is not required before the labeling is used.

Although not required for approval of this supplement, please consider the following recommendations from the Division of Medical Errors and Technical Support (DMETS) for labeling revisions at the next printing:

A. GENERAL COMMENT

Per CFR 21 201.10(g)(2), increase the prominence of the established name so that it is at least ½ the size of the proprietary name.

B. INSERT LABELING

The package insert states that a *test dose* should be given because of a *potential allergic reaction* to secretin. However, this information is listed in the *WARNINGS* section and is not repeated in the *DOSAGE AND ADMINISTRATION* section. We recommend that this information should also be included in the *DOSAGE AND ADMINISTRATION* section of the package insert.

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}

Brian E. Harvey, M.D., Ph.D.
Director
Division of Gastroenterology 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
9/12/2005 03:36:00 PM
for Dr. Brian Harvey