DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-136/S-009

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 March 15, 2004, received March 15, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for SecreFlo (secretin) for Injection.

This supplemental application proposes the following changes:

- Replace all instances of SecreFlo™ with SecreMax™
- Replace all instances of Repligen with ChiRhoClin
- Replace any address for Repligen with ChiRhoClin's address

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, immediate container and carton labels submitted March 15, 2004).

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-009. 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. Container Label

1. Increase the prominence of the established name.

2. Revise the statement of strength to read "16 mcg/vial," and increase the prominence.

3. Insert the statement, "Discard unused portion," after the "For single use only," statement.

4. In the "For reconstitution, dosage and administration…" paragraph, insert the statement "After reconstitution, each mL contains 2 mcg/mL of secretin."

B. Carton Labeling

1. See comments A-1 through A-4.

2. Relocate the revised "After reconstitution…" statement to the side panel.

3. Include the net quantity (i.e., 1 vial) on the principal display panel.

C. Insert Labeling

Delete the trailing zeroes presented throughout the labeling since they could be misinterpreted (e.g. 6.0 as 60).

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 & 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
7/26/04 04:57:50 PM
for Dr. Robert Justice