DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-136
NDA 21-209

ChiRhoClin, Inc.
Attention: Edward Purich, Ph.D.
15500Gallaudet Avenue
Silver Spring, MD 20905

Dear Dr. Purich:

Please refer to your new drug applications (NDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for SecreFlo™ (secretin) for Injection.

NDA 21-136 was dated May 14, 1999, received May 25, 1999, and NDA 21-209 was dated August 17, 1999, received August 17, 1999.

For NDA 21-136, we acknowledge receipt of your submissions dated September 17, October 5, November 2, November 26, December 3, December 21, 2001, January 21, February 4, February 13, February 14, February 27, March 1, March 13, April 2, April 3, and April 4, 2002. Your submission of October 5, 2001 constituted a complete response to our November 7, 2000 action letter.

For NDA 21-209, we acknowledge receipt of your submissions dated October 5, November 2, November 26, December 21, 2001, January 22, February 13, March 1, March 22, and April 2, April 3, April 4, 2002. Your submission dated October 5, 2001 constituted a complete response to our February 3, 2000 action letter.

NDA 21-136 provides for the use of SecreFlo (secretin) for Injection for: the use in secretin stimulation testing for stimulation of pancreatic secretions, including bicarbonate, to aid in the diagnosis of pancreatic exocrine dysfunction.

NDA 21-209 provides for the use of SecreFlo (secretin) for Injection for: the use in secretin stimulation testing for stimulation of gastrin secretion to aid in the diagnosis of gastrinoma.

We have completed the review of these applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, the applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert. The FPL for the immediate container and carton labels must be identical to the labeling text for the labels submitted April 3, 2002. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 21136." Approval of this submission by FDA is not required before the labeling is used.

We remind you of the postmarketing commitments that you agreed to in your submission dated March 13, 2002 and in your April 2, 2002 teleconference with Dr. Art Shaw of this Division.

1. Develop an assay for impurities in the drug product

Final Report Submission: Within nine months of the date of this letter

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Postmarketing Study Protocol", "Postmarketing Study Final Report", or "Postmarketing Study Correspondence."**

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens must contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (21 CFR 314.55).

Your application does not address the pediatric study requirements. Submit your pediatric drug development plans or a request for a waiver, if you believe one is appropriate, within 120 days from the date of this letter. If you believe a waiver is justified, submit your request with supporting information and documentation.

Pediatric studies conducted under the terms of section 505A of the Federal Food, Drug, and Cosmetic Act may result in additional marketing exclusivity for certain products (pediatric exclusivity). You should refer to the *Guidance for Industry on Qualifying for Pediatric Exclusivity* (available on our web site at www.fda.gov/cder/pediatric) for details. If you wish to qualify for pediatric exclusivity you should submit a "Proposed Pediatric Study Request" (PPSR) in addition to your plans for pediatric drug development described above. We recommend that you submit a Proposed Pediatric Study Request within 120 days from the date of this letter. If you are unable to meet this time frame but are interested in pediatric exclusivity, please notify the division in writing. FDA generally will not accept studies submitted to an NDA before issuance of a Written Request as responsive to a Written Request. Sponsors should obtain a Written Request before submitting pediatric studies to an NDA. If you do not submit a PPSR or indicate that you are interested in pediatric exclusivity, we will review your pediatric drug development plan and notify you of its adequacy. Please note that satisfaction of the requirements in 21 CFR 314.55 alone may not qualify you for pediatric exclusivity. FDA does not necessarily ask a sponsor to complete the same scope of studies to qualify for pediatric exclusivity as it does to fulfill the requirements of the pediatric rule.

21 CFR 312.34 (a) allows access to an unapproved drug in certain situations by means of a treatment protocol. Upon commercial availability of SecreFlo, you will need to cease enrollment of patients into your treatment protocol under (b)(4)---------

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit 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, Maryland 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Alice Kacuba, R.N., MSN, RAC, Regulatory Health Project Manager, at (301) 827-1602.

Sincerely,

{See appended electronic signature page}

Victor F. C. Raczkowski, M.D., M.Sc.
Acting Director
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

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
4/4/02 03:54:54 PM
for Dr. Victor Raczkowski