



NDA 21-256/S-001

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 April 19, 2004, received April 20, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Human Secretin for Injection, a synthetic lyophilized sterile powder.

This supplemental application proposes the proprietary names ChiRhoStim™ (b)(4)----- (b)(4)----- for Human Secretin for Injection.

We completed our review of this application and the proprietary name ChiRhoStim™ is acceptable, effective on the date of this letter.

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 21-256/S-001. 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}

Joyce Korvick, M.D., M.P.H
Acting 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
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/s/

Joyce Korvick
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