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## Important Drug Information Update IMPORTANT DRUG WARNING

May 20, 2014

Proprietary Name: **ChiRhoStim®** Generic Name: **Secretin – Human**  
Lot Number Affected: **0636149**

### **Attention: Precautionary Measures to Assure No Possible Microbiological Contamination**

Dear Health Care Provider:

In order to alleviate the current critical shortage of ChiRhoStim® (Human Secretin for Injection), ChiRhoClin, Inc. (ChiRhoClin) is coordinating with the U.S. Food and Drug Administration (FDA) to increase the availability of the drug. At this time, FDA does not object to the release of batch #0636149, provided there is an additional level of assurance to protect against any theoretical possibility of microbiological contamination. This batch was produced at a new manufacturing facility that has not been approved by the FDA. During the manufacture of ChiRhoStim® batch #0636149, all test results and media fills show no contamination at the facility.

As a precaution against any possible microbial contamination, ChiRhoClin is instructing all medical personnel administering ChiRhoStim® to:

**USE THE MILLEX-GV SYRINGE MICROBIAL FILTER UNIT (0.22 µm, PVDF, 33 MM, GAMMA STERILIZED) PRIOR TO ADMINISTERING CHIRHOSTIM® (HUMAN SECRETIN FOR INJECTION) BATCH 0636149**

### **THE MICROBIAL FILTERS ARE INCLUDED WITH EACH VIAL OF CHIRHOSTIM®**

Please refer to the package insert for additional information on reconstituting ChiRhoStim®.

**ChiRhoClin requests that healthcare providers immediately report any difficulty in using the modified administration procedure for ChiRhoStim® to 301-476-8388.** ChiRhoClin will keep healthcare providers informed of any new information which becomes available.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program online, by regular mail or by fax.

- **Online:** [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- **Regular Mail:** use postage-paid, pre-addressed Form FDA 3500 available at: [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm). Mail to address on the pre-addressed form.
- **Telephone:** 1-800-332-1088
- **Fax:** 1-800-FDA-0178

This letter is being distributed with the knowledge of the U.S. Food & Drug Administration.

Thank you for your cooperation,

Edward D. Purich  
President/CEO of ChiRhoClin, Inc. (301-476-8388)