

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-136

21-209

MICROBIOLOGY REVIEW(S)

4 Page(s) Withheld

**Review for Division of Gastrointestinal and Coagulation Drug Products, HFD-180
Office of New Drug Chemistry, Microbiology Staff, HFD-805
Microbiologists's Review No. 2**

October 13, 2000

MICROBIOLOGY REVIEWER: Carol K. Vincent

A. 1. **NDA No.:** 21-136

DRUG PRODUCT NAME: Synthetic Porcine Secretin

APPLICANT:

ChiRhoClin, Inc.
15500 Gallaudet Avenue
Silver Spring, MD 20905-4176

MANUFACTURER:

Chesapeake Biological Laboratories, Inc.
Camden Industrial Park
1111 South Paca Street
Baltimore, MD 212300-2591

2. **DOSAGE FORM AND ROUTE OF ADMINISTRATION:**
Sterile, lyophilized powder.

3. **METHOD(s) OF STERILIZATION:**

4. **PHARMACOLOGICAL CATEGORY AND/OR PRINCIPAL INDICATION:**
Diagnosis of pancreatic exocrine disease.

5. **DRUG PRIORITY CLASSIFICATION:** 3 S

B. 1. **AMENDMENT DATE:** February 18, 2000 [partial response]
2. **AMENDMENT RECEIVED FOR REVIEW:** March 3, 2000
3. **AMENDMENT DATE:** May 8, 2000 [remainder of response]
4. **AMENDMENT RECEIVED FOR REVIEW:** June 2, 2000
5. **RELATED DOCUMENTS:** NDA 21-209, dated August 17, 1999;
DMF _____, amended February 14, 2000 and May 5, 2000
with duplicates of the amendments to NDA 21-136

C. **REMARKS:** Previously, all sterilization process validation information in support of NDA 21-136 and 21-209 was contained within DMF _____ for Chesapeake Biological Laboratories, subject of Microbiologist's Review No. 1, dated February 2, 2000. The applicant has amended the relevant NDAs 21-136 and 21-209, and duplicate to DMF _____ with the same information that is subject of the two amendments identified above, subject of this review.

NDA 21-209 references NDA 21-136 in its entirety for the sterilization process validation information.

D. **CONCLUSION and RECOMMENDATION:** Recommend approval from the microbiology perspective on the basis of sterility assurance. All issues have been satisfactorily resolved; there are no additional outstanding issues.

CC:
Orig. NDA 21-136
Orig. NDA 21-209
HFD-160/Consult/CKVincent [HFD-805]
HFD-180/AShaw/BStrongin
Drafted by:-CKVincent/07-27-2000/10-12-2000
Filename:C:\CKV99\NDA21136.2ND

[/S/]
Carol Keller Vincent 10-13-2000
Review Microbiologist [HFD-805]

[/S/] 10/14/00

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Review for Division of Gastrointestinal and Coagulation Drug Products, HFD-180
Office of New Drug Chemistry, Microbiology Staff, HFD-805
Microbiologists's Review No. 1

February 2, 2000

MICROBIOLOGY REVIEWER: Carol K. Vincent

A. 1. NDA No.: 21-209

DRUG PRODUCT NAME: Synthetic Porcine Secretin

APPLICANT:

ChiRhoClin, Inc.
15500 Gallaudet Avenue
Silver Spring, MD 20905-4176

DRUG PRODUCT MANUFACTURER:

Chesapeake Biological Laboratories, Inc.
Camden Industrial Park
1111 South Paca Street
Baltimore, MD 212300-2591

2. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
Sterile, lyophilized powder.

3. METHOD(S) OF STERILIZATION: →

4. PHARMACOLOGICAL CATEGORY AND/OR PRINCIPAL INDICATION:
Diagnosis of gastrinoma | —

5. DRUG PRIORITY CLASSIFICATION: 3 P

B. 1. DOCUMENT DATE: August 17, 1999

2. DOCUMENT RECEIVED FOR REVIEW: November 17, 1999

3. COMIS USER FEE DUE DATE: June 17, 2000

4. RELATED DOCUMENT: DMF → dated September 13, 1999

5. DMF RECEIVED FOR REVIEW: October 18, 1999

C. REMARKS: This application's sterilization process validation information is identical to NDA 21-136; the same review applies in every respect to both NDA 21-209 and NDA 21-136. NDA 21-209 is for a clinically different indication than NDA 21-136, and was filed separately.

D. CONCLUSION and RECOMMENDATION:

NDA 21-209 references NDA 21-136 [and DMF → , for the CMC / sterilization process validation information - Microbiology information. Neither the application, NDA 21-136, nor the contract manufacturer's DMF — contains an adequate amount of sterilization process validation information for the subject drug product. We recommend approvable from the microbiology prospective, *pending satisfactory review of additional and clarifying information from the DMF Holder.* See "E. REVIEW NOTES:" and "Draft of Letter to Applicant", below.

CC:

Orig. NDA 21-209
HFD-160/Consult/CKVincent [HFD-805]
HFD-180/AShaw/BStrongin
Drafted by: CKVincent/01-31-2000

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Carol K. Vincent 02-04-2000
Review Microbiologist [HFD-805]

Filename: C:\CKV99\NDA21209.DMF

PKC 2/7/00

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