CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

21-136/S006

Trade Name: SecreFlo Injection

Generic Name: (synthetic secretin)

Sponsor: ChiRhoClin, Inc.

Approval Date: March 1, 2004

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-136/ S006

CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	X
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Labeling	X
Medical Review(s)	
Chemistry Review(s)	X
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	X
Clinical Pharmacology/ Biopharmaceutics Review(s)	X
Administrative/Correspondence Document(s)	X

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-136/ S006

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-136/S-006

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 August 11, 2003, received August 13, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for SecreFlo™ (synthetic secretin) Injection.

We acknowledge receipt of your submission dated December 23, 2003, which constituted a complete response to our December 12, 2003 action letter.

This supplemental new drug application provides for a change in formulation for secretin. This supplement has been administratively split from your supplemental new drug application (S-005) which provides for a change in manufacturing site. Further communication regarding S-005 will be sent to you under separate cover.

We completed our review of this application, as amended. This application 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 submitted August 11, 2003).

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-006." 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}

Robert L. Justice, M.D., M.S.
Director
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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/s/

Joyce Korvick
3/1/04 03:55:40 PM
for Dr. Robert Justice

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-136/S006

NOT-APPROVABLE LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-136/S-006

ChiRhoClin, Inc.
Attention: Edward D. Purich, Ph.D.
4000 Blackburn Lane, Suite 270
Burtonsville, MD 20866-6129

Dear Dr. Purich:

Please refer to your supplemental new drug application dated August 11, 2003 received August 13, 2003 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for SecreFlo™ (synthetic secretin) Injection, 16 mcg/vial.

We also refer to our teleconferences with you dated February 13, 2003 and March 4, 2003.

This supplemental new drug application (S-006) provides for a change in formulation for secretin. This supplement has been administratively split from your supplemental new drug application (S-005) which provides for a change in manufacturing site. Further communication regarding S-005 will be sent to you under separate cover.

We completed our review and find the information presented is inadequate, and the supplemental application (S-006) is not approvable under section 505(d) of the Act and 21 CFR 314.125(b). The deficiencies are summarized as follows:

- You need to adequately address

Within 10 days after the date of this letter, you are required to amend the supplemental application (S-006), notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.120. If you do not follow one of these options, we will consider your lack of response a request to withdraw the application under 21 CFR 314.65. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

This product may be considered to be misbranded under the Federal Food, Drug, and Cosmetic Act if it is marketed with this change before approval of this supplemental application.

If you have any questions, call Mr. Ryan Barraco at (301) 827-0191.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D., M.S.
Director
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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/s/

Joyce Korvick
12/12/03 05:26:19 PM
for Dr. Robert Justice

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-136/S006

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW # 1	1. Organization: HFD-180	2. NDA number: 21-136	
3. Name and Address of Applicant (City & State): ChiRhoClin, inc. 4000 Blackburn Lane, Suite 270 Burtonsville, MD 20866-6129		4. AF Number: 5. Supplement(s)	
6. Name of Drug: SecreFlo™	7. Nonproprietary Name: Secretin	Number: SCM 005 SCF 006	Date: August 11, 2003 August 11, 2003
8. Supplement Provides for: 1- Change in manufacturing site from [redacted] to Bell-More Labs 2- L-Cysteine excipient was reduced from 15mg/vial to 1mg/vial 3- [redacted] saline for injection [redacted] sodium chloride)		9. Amendments & Other (Reports, etc.) Dates: Amendment dated 09/08/03 Amendment dated 09/30/03 Amendment dated 10/21/03	
10. Pharmacological Category:	11. How Dispensed: RX X OTC	12. Related Submission/ DMF(s):	
13. Dosage Form: Granule	14. Potency: 15 mg and 30 mg		
15. Chemical Name and Structure: p-Gly-Thr-Phe-Thr-Ser-Glu-Leu-Ser-Arg-LeuArg-Asp-Ser-ala-arg-Leu-Gln-Arg-Leu-Leu-Gln-Gly-Leu-Val-NH_2 Molecular Formula: $C_{130}H_{220}N_{44}O_{41}.(CH_3COOH_2.H_2O_2)_2$ (Acetate form) Molecular Weight: 3055.5		16. Records and Reports: Current Yes X No	

17. Comments:
Acceptable Establishment Evaluation Report (EER) for the all the sites described in the supplement.
Dates of the EER Report: September 12 and November 04, 2003.
Micro Consult: pending
Biopharm Consult: pending
CC: NDA 21-136
HFD-180/Div File/NDA 21-136/S005/006
HFD-180/R. Justice
HFD-181/B.Scorggs
HFD-180/L.Zhou
HFD-180/A.Al-Hakim
11-06-03 \Wordfiles\NDA Supplements 21136005/006

18. Conclusions and Recommendations:
From my CMC point of view, the supplement is recommended for approval, however, because Biopharm and Micro consult reviews are pending, the final regulatory action should be taken after receiving the recommendation of Micro and Biopharm reviews.

19.Reviewer Name: Ali Al-Hakim, Ph.D.	Date Completed: November 6, 2003

3 Page(s) Withheld

✓ § 552(b)(4) Trade Secret / Confidential

_____ § 552(b)(4) Draft Labeling

_____ § 552(b)(5) Deliberative Process

Withheld Track Number: Administrative- 21-136
5006

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/s/

Ali Al-Hakim
11/6/03 02:10:58 PM
CHEMIST
Linag: This is the same review we signed for supplement 005 but supplement 5 is linked to supplement 006 (SCF). Therefore, this review covers supplement 006 as well.

Liang Zhou
11/6/03 02:20:23 PM
CHEMIST

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-136/S006

MICROBIOLOGY REVIEW

Product Quality Microbiology Review
Review for HFD 180
17-November-2003

NDA:	21-136/SCF006
Drug Product Name:	SecreFlo
Non-proprietary	Secretin
Drug Product Classification:	
Review Number:	1
Subject of this Review	
Submission Date:	August 11, 2003
Receipt Date:	August 13, 2003
Consult Date:	October 9, 2003
Date Assigned for Review:	October 9, 2003
Submission History (for amendments only)	
Date(s) of Previous Submission(s):	
Date(s) of Previous Micro Review(s):	
Applicant/Sponsor	
Name:	ChiRhoClin, Inc.
Address:	4000 Blackburn Lane, Suite 270 Burtonsville, MD 20866-6129
Representative:	Edward D. Purch
Telephone:	301-476-8388
Name of Reviewer:	Stephen E. Langille, Ph.D.
Conclusion:	Recommended for approval

Product Quality Microbiology Data Sheet

A. 1. **TYPE OF SUPPLEMENT:** Prior approval

2. **SUPPLEMENTS PROVIDE FOR:** A change in the product formulation.

3. **MANUFACTURING SITE:** Bell-More Labs, Inc.
4030 Gill Ave.
Hampstead, MD 21074-0179

4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**

- Intravenous Injection
- Lyophilized powder
- 16 ug

5. **METHOD(S) OF STERILIZATION:**

6. **PHARMACOLOGICAL CATEGORY:** Diagnosis of exocrine disfunction and gastroma

B. **SUPPORTING/RELATED DOCUMENTS:** None

C. **REMARKS:** The Applicant has requested an expedited review . Supplement SCF-006 provides for a modification in the drug product formulation.

filename: c:\reviews\21-136scf006r1.doc

Executive Summary

I. Recommendations

A. Recommendation on Approvability -
NDA 12-136/SCF006 is recommended for approval.

B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable -
Not applicable

II. Summary of Microbiology Assessments

A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology -
A new product formulation will be used for SecreFlo.

B. Brief Description of Microbiology Deficiencies -
No deficiencies were identified based upon the information provided.

C. Assessment of Risk Due to Microbiology Deficiencies -
Not applicable

III. Administrative

A. Reviewer's Signature _____

B. Endorsement Block
Stephen E. Langille, Ph.D.
Peter Cooney, Ph.D.

C. CC Block
In DFS

Product Quality Microbiology Assessment

Supplement SCF-006 provides for a change in the drug product formulation. The L-Cysteine excipient will be reduced from 15 mg/vial to 1 mg/vial

saline for injection.

SecreFlo®.

old product formulation. However,

Satisfactory

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/s/

Stephen Langille
11/18/03 11:55:34 AM
MICROBIOLOGIST

Peter Cooney
11/18/03 12:23:20 PM
MICROBIOLOGIST

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-136/ S006

CLINICAL PHARMACOLOGY AND BIOPHARMACEUTICS REVIEW(S)

Clinical Pharmacology and Biopharmaceutics Review

NDA: 21-136 / SCF-006 AZ **Stamp Date**: 12/30/03

Trade Name: Secreflo® Injection

Active Ingredient: Synthetic Porcine Secretin

Sponsor: ChiRhoClin, Inc.

Reviewer: Suliman I. Al-Fayoumi, Ph.D.

Type of Submission: Amendment to Prior-Approval Supplement

Background

Secreflo® (Synthetic Porcine Secretin) is currently approved in the US for 1) diagnosis of pancreatic exocrine disease, [redacted] diagnosis of gastrinoma (Zollinger-Ellison Syndrome) & 4) facilitation of pancreatic duct cannulation during ERCP. Secreflo® is marketed as lyophilized sterile powder for I.V. injection.

Supplement SCM-006 was submitted in support of the sponsor's proposal to change the manufacturing facility from [redacted] to Bell-More Labs and reformulate Secreflo® to reduce the L-Cysteine excipient from 15 mg/vial to 1 mg/vial as [redacted] saline for injection.

In the supplement, the sponsor submitted 3-month stability data on Bell-More Labs Porcine Secretin batches as well as endotoxin and microbiological tests. [redacted]

sponsor needed to adequately address [redacted] Secreflo® (See CPB Review dated 12/11/03).

In response, among other arguments, the sponsor has submitted additional *in vivo* data derived from the cat model bioassay demonstrating that [redacted] within [redacted] of the specified label claim (Table 1) [redacted] (for a detailed description of the cat model bioassay, see Pharm/Tox Review of NDA 21-136 dated 3/29/00).

Reviewer's Comments & Recommendations

From the viewpoint of the Office of Clinical Pharmacology and Biopharmaceutics (OCPB/Division of Pharmaceutical Evaluation II) the sponsor's request for biowaiver for Secreflo® I.V. injection is **acceptable**.

Table 1. Summary of the cat bioassay and HPLC results by batch

Porcine Secretin batches with L-Cysteine 1 mg/vial		
Batch	Absolute bioavailability in cat (% label)	HPLC assay (% label)
824553		
234605		
234604		
Porcine Secretin batches with L-Cysteine 15 mg/vial		
1100-7		
1100-9		
1746-1		

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/s/

Suliman Alfayoumi
2/10/04 09:59:56 AM
BIOPHARMACEUTICS

Suresh Doddapaneni
2/10/04 03:06:29 PM
BIOPHARMACEUTICS

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-136/ S006

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 21-136/S-006

ChiRhoClin, Inc.
Attention: Edward D. Purich, Ph.D.
President and CEO
4000 Blackburn Lane, Suite 270
Burtonsville, MD 20866-6129

Dear Dr. Purich:

We acknowledge receipt on December 30, 2003 of your December 23, 2003 resubmission to your supplemental new drug application for SecreFlo (secretin) lyophilized sterile powder.

This amendment constitutes a complete response to our December 12, 2003 action letter. The goal date is April 30, 2004.

If you have any question, call me at (301) 443-8017.

Sincerely,

{See appended electronic signature page}

Ryan Barraco, B.A., B.S.
Consumer Safety Officer
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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/s/

Ryan Barraco
2/12/04 09:20:21 AM

Division of Gastrointestinal & Coagulation Drug Products

REGULATORY PROJECT MANAGER REVIEW

Application Number:	21-136/SCM-005 and SCM-006
Name of Drug:	SecreFlo™ (synthetic secretin)
Sponsor:	ChiRhoClin

Material Reviewed

Submission Date:	August 11, 2003
Receipt Date:	August 13, 2003

Background and Summary:

NDA 21-136 for SecreFlo™ (synthetic secretin) was approved April 4, 2002 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, a Type 6 NDA, was administratively added to allow for the review of an additional indication for SecreFlo™ and was approved on April 4, 2002 for the use in secretin stimulation testing for stimulation of gastrin secretion to aid in the diagnosis of gastrinoma.

Supplement 005 was administratively split into SCM-005 and SCF-006 to provide for two changes: a change in drug product manufacturing site and a change in formulation respectively. The submitted proposed package insert addresses these changes.

Review

Deletions are shown as ~~strikeouts~~ and additions are shown as double underlines. The following revisions were noted.

Package insert

The submitted draft package insert, identified as "July 2003 ChiRhoClinP101012" was compared to the draft package insert, identified as "sNDAChiRhoClinPI0101" and approved on draft November 1, 2002 from Supplement S-001.

1. In the DESCRIPTION section, the first line of the fourth paragraph has been revised to read as follows:

   "SecreFlo™ contains 16 mcg of purified secretin, ~~15~~ 1 mg of L-cysteine hydrochloride, 20 mg of mannitol, and sodium chloride to make isotonic per vial."

Comment: These are acceptable revisions pending the chemistry review.

2. In the HOW SUPPLIED section, the following revisions have been made:

"SecreFlo™ is a registered trademark of Repligen Corporation Waltham, MA.

~~Marketed by:~~
~~Repligen Corporation~~
~~Waltham, MA 02453~~

~~Distributed by:~~Manufactured for:
ChiRhoClin, Inc.
~~Silver Spring~~, Burtonsville, MD ~~20905~~ ~~nd~~

~~Integrated Commercialization Solutions~~
~~Addison, TX 75001~~

Manufactured by:
Bell-More Labs, Inc.
Hampstead, MD 21074

~~April 2002~~ July 2003
~~sNDAChiRhoClinP10101~~ ChiRhoClinPI01012,"

Comment: These revisions reflect the change in manufacturing site and reflect corporate relationships. These revisions are acceptable.

Conclusions

The submitted labeling is acceptable pending completion of the chemistry review, clinical pharmacology review and medical review.

Betsy Scroggs, Pharm. D.
Consumer Safety Officer

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/s/

Betsy Scroggs
12/5/03 05:33:28 PM
CSO

Brian Strongin
12/9/03 08:38:03 AM
CSO

CENTER FOR DRUG EVALUATION AND RESEARCH
MEDICAL NECESSITY DETERMINATION

INSTRUCTIONS

Please evaluate the medical need for this product by answering the questions below. Keep in mind that a medically necessary drug product is a product that is used to treat or prevent a serious disease or medical condition for which there is no other alternative drug that is judged by medical staff to be an adequate substitute. Patient "inconvenience" alone is an insufficient basis to classify a product as medical necessity.

NAME AND HFD NUMBER OF DIVISION:
Division of Gastrointestinal and Coagulation Drug Products HFD-180
Name of person(s) making determination: Dr. Gail Moreschi
Date of Medical Necessity Request: October 21, 2003
PRODUCT(S) SecreFlo™ (secretin) for Injection, 16 mcg/vial
MANUFACTURING FIRM for NDA 21-136 ChiRhoClin, Inc. contact Dr. Edward Purich at (301) 476-8388, fax (301) 476-9529
ChiRhoClin, Inc.
4000 Blackburn Lane, Suite 270
Burtonsville, MD 20866-6129

Single Source Product or multiple source product? Response: √Single-source product

BACKGROUND

SecreFlo™ (secretin), approved as an orphan drug is a GI diagnostic agent. Currently, the firm has 4 CMC supplements with us to extend the expiry (CBE30) on the current lot, another supplement to change his manufacturing site, another to change the formulation, and another to add a testing site. Although the expiry date is a CBE30 and could be implemented now

The sponsor has asked for an expedited review for the change in manufacturer and change in formulation. We are pending

1. Is the product used to treat a serious disease or medical condition?

[ ] No
[x] Yes – Explain - Pancreatic exocrine dysfunction is a serious diagnosis. Gastrinoma is a life-threatening diagnosis and secretin can be used to diagnose gastrinoma that can otherwise be missed.

2. What are the labeled indications for this product?

1) Stimulation of pancreatic secretions, including bicarbonate, to aid in the diagnosis of pancreatic exocrine dysfunction.
2) Stimulation of gastrin secretion to aid in the diagnosis of gastrinoma.

3) Stimulation of pancreatic secretions to facilitate the identification of the ampulla of Vater and accessory papilla during endoscopic retrograde cholangiopancreatography (ERCP).

3. Are there important "off label" uses such as those for a serious medical condition?

4. Are there generic forms of this product?
[√] No
[NA] Yes—Are there any special benefits/risks associated with the generic product(s)?

5. Are there alternative products available?
[X] No The firm has NDA 21-256, human secretin; it is not on the market.
[ ] Yes – Please explain the risk(s) and benefit(s) of this alternative product. NDA 21-256 is approvable. The firm has just made a class 2 resubmission.

6. From the above assessment, is this product Medically Necessary?
(Please note that this question refers only to the overall Medical Necessity of the product(s), not whether the specific (manufacturer's) product in question is appropriate for continued administration to patients. If the product is determined to be Medically Necessary, an assessment will then be made as to whether the product in question may be used (for instance with additional testing if necessary) to alleviate shortage situations. If it is not appropriate to administer such material to patients then alternative approaches will be examined. When necessary, a separate Health Hazard Evaluation [HHE] will be requested to address newly identified defects, impurities and/or risks associated with this drug.)

[ ] No
[X] Yes (Please state if this is only for specific indications)

7. Additional comments: None.

8. Signature of person performing this medical necessity determination.

{See appended electronic signature page}

Medical Officer Date

{See appended electronic signature page}

Medical Officer, Team Leader Date

{See appended electronic signature page}

Division Director Date

(MNForm-Revised 10/02)

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/s/

Robert Justice
11/10/03 05:22:06 PM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

REQUEST FOR CONSULTATION

TO *(Division/Office)*: Office of Pharmaceutical Science
HFD-805 Microbiology Attn: Patricia Tuegel
PKLN Rm 18B08
5600 Fishers Lane
Rockville, MD 20857
(301) 827-7340

FROM: **Betsy Scroggs, Pharm. D.**
Consumer Safety Officer
Division of Gastrointestinal and Coagulation Drug Products, HFD 180
Center for Drug Evaluation and Research
Food and Drug Administration
Tel: (301) 827-1250 Fax: (301) 827-1305
Email: scroggsb@cder.fda.gov

DATE: October 9, 2003	IND NO. N/A	NDA NO. 21-136	TYPE OF DOCUMENT: SCP-005 & SCF-006	DATE OF DOCUMENT August 11, 2003

NAME OF DRUG	PRIORITY CONSIDERATION	CLASSIFICATION OF DRUG	DESIRED COMPLETION DATE
SecreFlo 16 mcg for Injection (lyophilized powder)	High- 30 days	GI Diagnostic Agent	November 11, 2003

NAME OF FIRM: ChiRhoClin

REASON FOR REQUEST

I. GENERAL

X MANUFACTURING CHANGE/ADDITION

COMMENTS/SPECIAL INSTRUCTIONS:

Background: HFD-180 requests a microbiology consult for submission NDA 21-136/SCM-005 & SCF-006. The letter date is August 11, 2003 and the User Fee Goal date is December 13, 2003. SecreFlo is an acetate salt of secretin, a peptide hormone containing 16 mcg of purified secretin, 15 mg of L-cysteine hydrochloride, and 20 mg of mannitol per vial. It was approved April 4, 2003 for use in secretin stimulation testing for: 1) Stimulation of pancreatic secretions, including bicarbonate, to aid in the diagnosis of pancreatic exocrine dysfunction and, 2) Stimulation of gastrin secretion to aid in the diagnosis of gastrinoma. These supplements provide for a change in manufacturing site and a change in formulation.

The sponsor has asked for an expedited review. In several conversations recently with the firm, they have expressed concern

This is a very small company with this drug as their only approved product. It was approved as an orphan drug.

Thank you. I can be reached at 7-1250.

SIGNATURE OF REQUESTER: Betsy Scroggs	METHOD OF DELIVERY (Check one) x MAIL ☐ HAND
SIGNATURE OF RECEIVER	SIGNATURE OF DELIVERER

Wpfiles\template-full-consult-form.doc

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/s/

Betsy Scroggs
10/9/03 02:30:44 PM