CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
NDA 21-107/S006

Trade Name: Lotronex Tablets

Generic Name: alosetron hydrochloride

Sponsor: GlaxoWellcome, Inc.

Approval Date: June 3, 2002

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 21-107/S006

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Reviews / Information Included in this NDA Review.	
Approval Letter	X
Approvable Letter	
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Medical Review(s)	
Chemistry Review(s)	X
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/ Biopharmaceutics Review(s)	
Administrative/Correspondence Document(s)	

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 21-107/S006

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-107/S-006

GlaxoSmithKline
Attention: Kim M. Tyndall
Assistant Director, CMC Post Approval Regulatory Affairs
Five Moore Drive
P.O. Box 13398
Research Triangle Park, North Carolina 27709-3398

Dear Ms. Tyndall:

We acknowledge receipt of your supplemental new drug application dated April 16, 2002, received April 17, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lotronex (alosetron HCl) Tablets.

This "Changes Being Effected in 30 Days" supplemental new drug application provides for the qualification of [redacted] HDPE bottle to contain 30-tablets of Lotronex®.

We have completed the review of this supplemental application, and it is approved.

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 Paul E. Levine, Jr., R.Ph., Regulatory Project Manager, at (301) 827-7310.

Sincerely,

{See appended electronic signature page}

Liang Zhou, Ph.D.
Chemistry Team Leader for the
Division of Gastrointestinal
and Coagulation Drug Products, (HFD-180)
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Liang Zhou
6/3/02 05:46:52 PM

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APPLICATION NUMBER:

NDA 21-107/S006

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW	1. Organization: HFD-180	2. NDA Number: 21-107
3. Name and Address of Applicant (City & State): GlaxoSmithKline One Franklin Plaza P.O. Box 7929 Philadelphia, PA 19101		4. AF Number: Supplement(s)
6. Name of Drug: Lotronex® Tablets	7. Nonproprietary Name: Alosetron hydrochloride	Number(s): CBE SCP006 / Date(s): Apr 16, 02
8. Supplement Provides for: A new 30 tablet count bottle for Lotronex® (alosetron hydrochloride) Tablets, 1mg. Consist in a [redacted] HDPE bottle with a [redacted]		9. Amendments and Other (Reports, etc.) Dates: None
10. Pharmacological Category: Treatment of Diarrhea-Predominant Irritable Bowel Syndrome (IBS) in women that have failed to respond to traditional therapy	11. How Dispensed: Rx	12. Related IND/NDA/DMF(s): NDA 21-2107
13. Dosage Form: Tablets	14. Potency 1 mg	
15. Chemical Name and Structure: Refer to Original NDA 21-107		16. Records and Reports: Current Yes _ No Reviewed Yes _ No

17. Comments: See Review Notes.

cc: NDA 21-107/S006
HFD-180/Div File
HFD-181/PLevine
HFD-180/VRaczkowski
HFD-180/MYsern
R/D init by:LZhou
typist:/ MY c:\word\sup 21107006.1my

18. Conclusions and Recommendations:

The data that is provided in this supplement is enough to support the proposed change. This supplement can be approved.

19. Reviewer

Name:	Signature	Date Completed:
Maria E. Ysern		April 26, 02

Form FDH 2266 (7/75) ALT R

3 Page(s) Withheld

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

_____ § 552(b)(4) Draft Labeling

_____ § 552(b)(5) Deliberative Process

Withheld Track Number: Chemistry- 21-107
S006

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/s/

Maria Ysern
5/20/02 12:54:13 PM
CHEMIST

Ali Al-Hakim
5/20/02 01:18:48 PM
CHEMIST
Ali Al-Hakim for Liang Zhou