

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-695/S-003

ADMINISTRATIVE DOCUMENTS
AND
CORRESPONDENCE

Dir. file

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-695/S-004

JUN 16 1998

Glaxo Wellcome
Five Moore Drive
Research Triangle Park, NC 27709

Attention: Besty J. Waldheim
Project Director
Regulatory Affairs

Dear Ms. Waldheim:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Raxar™ (grepafloxacin hydrochloride) Tablets

NDA Number: 20-695

Supplement Number: S-004

Date of Supplement: June 3, 1998

Date of Receipt: June 4, 1998

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on August 3, 1998 in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

Food and Drug Administration
Division of Special Pathogens and
Immunologic Drug Products, HFD-590
Office of Drug Evaluation IV
Center for Drug Evaluation and Research
Attention: Document Control Room
5600 Fishers Lane
Rockville, MD 20857

Sincerely,



Ellen C. Frank, R.Ph.
Acting Chief, Project Management Staff
Division of Special Pathogens and
Immunologic Drug Products, HFD-590
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

APPEARS THIS WAY
ON ORIGINAL



Division of Special Pathogens and Immunologic Drug Products

Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Boulevard, HFD-590
Rockville, MD 20850

FACSIMILE TRANSMISSION

DATE: 9/8/98

Number of Pages (including cover sheet): 1

TO: Bob Watson/Betsey Waldheim

COMPANY: GlaxoWellcome

FAX NUMBER: (919) 483-5756

MESSAGE: RE: NDA 20-695 (Raxar), SLR-003

Peter Dionne, the microbiologist for this NDA, has reviewed this supplement dated 3/31/98 and has the following response:

1. *Legionella pneumophila* may be added to the *in vitro* activity list of the package insert.



NOTE: We are providing the attached information via telefacsimile for your convenience. This material should be viewed as unofficial correspondence. Please feel free to contact me if you have any questions regarding the contents of this transmission.

FROM: Robin Anderson, RN, MBA

TITLE: Project Manager

TELEPHONE: (301) 827-2127

FAX NUMBER: (301) 827-2520

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cc: NDA 20-695
HFD-590/ Div. File
HFD-590/ P. Dionne

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

CDER GERIATRIC USE SUPPLEMENT

NDA/NUMBER:

26-695

SUPPLEMENT/NUMBER:

SLR-006

LETTER DATE:

8-26-98

SUPPLEMENT SUBMITTED UNDER 21 CFR 201.57(f) (10)

(See back of form for complete definitions.)

PLEASE CHECK ALL THAT APPLY

- | | | | |
|--|--------------------------------|-------------------------------|--------------------------------|
| <input type="checkbox"/> (i) | <input type="checkbox"/> (iv) | <input type="checkbox"/> (v) | <input type="checkbox"/> (vii) |
| <input checked="" type="checkbox"/> (ii) | <input type="checkbox"/> (iii) | <input type="checkbox"/> (vi) | |

CLINICAL EFFICACY TRIALS:

- | | |
|--|--|
| <input type="checkbox"/> Raw data/Study Analyses | <input checked="" type="checkbox"/> Not Applicable |
| <input type="checkbox"/> Literature | |

PHARMACOKINETICS AND/OR PHARMACODYNAMICS:

- | | |
|--|--|
| <input type="checkbox"/> Raw data/Study Analyses | <input checked="" type="checkbox"/> Not Applicable |
| <input type="checkbox"/> Literature | |

SAFETY/ADVERSE REACTIONS: Not Applicable

Clinical Trials:

Anecdotal Report:

- | | |
|--|---|
| <input type="checkbox"/> Raw data/Study Analyses | <input type="checkbox"/> MedWatch/Form 3500 |
| <input type="checkbox"/> Literature | <input type="checkbox"/> Literature |

OTHER:

PROJECT MANAGER:

/S/

DATE:

9/3/98

PLEASE COMPLETE THIS FORM AND RETURN TO THE DOCUMENT ROOM FOR DATA ENTRY.



DF

NDA 20-695/S-003

Food and Drug Administration
Rockville MD 20857

APR 7 1998

Glaxo Wellcome Inc.
Five Moore Drive
Research Triangle Park, NC 27709

Attention: Betsy J. Waldheim
Project Director, Regulatory Affairs

Dear Ms. Waldheim:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: RAXAR™ (grepafloxacin hydrochloride) Tablets

NDA Number: 20-695

Supplement Number: S-003

Date of Supplement: March 31, 1998

Date of Receipt: April 1, 1998

**APPEARS THIS WAY
ON ORIGINAL**

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on May 31, 1998 in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

Food and Drug Administration
Division of Special Pathogens and
Immunologic Drug Products, HFD-590
Office of Drug Evaluation IV
Center for Drug Evaluation and Research
Attention: Document Control Room
5600 Fishers Lane
Rockville, MD 20857

Sincerely,

Ellen C. Frank, R.Ph.
Acting Chief, Project Management Staff
Division of Special Pathogens and
Immunologic Drug Products, HFD-590
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

NDA 20-695/S-003
Page 2

cc:

Original NDA 20-695/S-003
HFD-590/Div. Files
HFD-590/CSO/Fogarty, P.

SUPPLEMENT ACKNOWLEDGEMENT

**APPEARS THIS WAY
ON ORIGINAL**