CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

50-725 / S-021

Trade Name: Augmentin

Generic Name: (amoxicillin / clavulanate potassium)

Sponsor: GlaxoSmithKline

Approval Date: June 13, 2003

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APPLICATION NUMBER:

50-725 / S-021

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APPLICATION NUMBER:

50-725 / S-021

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-725/S-021

GlaxoSmithKline
Attention: David Desris, Pharm.D.
Assistant Director, Global Antibiotic CMC Regulatory Affairs
1250 South Collegeville Road
P. O. Box 5089
Collegeville, Pennsylvania 19426-0989

Dear Dr. Desris:

Please refer to your supplemental new drug application dated December 13, 2002, received December 16, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act Augmentin® (amoxicillin/clavulanate potassium) Oral Suspension, 200/28.5 mg per 5 mL. This application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the extension of the expiration date from 12 months to 18 months for the unit dose and multidose products.

We have completed our review of this supplemental new drug application, and it is approved effective on the date of this letter.

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Susmita Samanta. M.D., Regulatory Project Manager, at (301) 827-2125.

Sincerely,

{See appended electronic signature page}

James D. Vidra, Ph.D.
Chemistry Team Leader for the
Division of Anti-Infective Drug Products, HFD-520
Division of New Drug Chemistry III
Center for Drug Evaluation and Research

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/s/

Jim Vidra

6/13/03 02:41:21 PM

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APPLICATION NUMBER:

50-725 / S-021

CHEMISTRY REVIEW(S)

NDA Supplement Review
Chemistry, Manufacturing, and Controls
Division of Anti-Infective Drug Products (HFD-520)

1. **NDA NUMBER/SUPLEMENT:** 50-725/SCE-021
2. **REVIEW:** # 1
3. **REVIEW DATE(s):** 6/1/03
4. **LETTER DATE:** 12/13/02
5. **STAMP DATE:** 12/16/02; **DUE DATE:** 6/16/03
6. **SUPPLEMENT PROVIDES FOR:** an extension of the expiration date from 12 months to 18 months for the unit dose and multidose products.
7. **PREVIOUS DOCUMENTS:** None

SUBMISSION(S) BEING REVIEWED: Original Submission

8. **NAME AND ADDRESS OF APPLICANT**

GlaxoSmithkline
Oone Franklin Plaza
P.O. Box 7929, Philadelphia, PA 19101-7929
ATT: David Desris , Assistant Director of Regulatory Affairs
Phone: (610)-917-6365

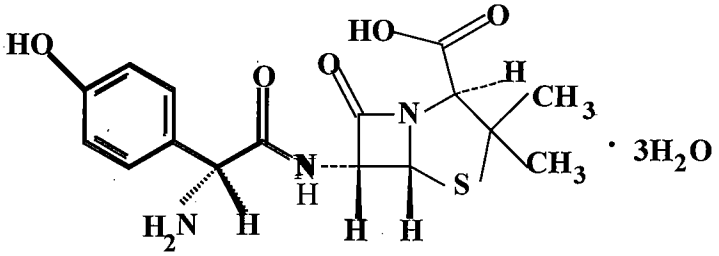
9. **DRUG PRODUCT NAME/(NONPROPRIETARY NAME):**

Augmentin powder for oral suspension / Amoxicillin/clavulanate potassium powder for oral suspension

10. **PHARMACOLOGICAL CATEGORY:** Anti-bacterial
11. **DOSAGE FORM:** Powder for oral suspension
12. **STRENGTH/POTENCY** 200mg/5ml
13. **ROUTE OF ADMINISTRATION:** Oral suspension
14. **Rx/OTC DISPENSED:** √ Rx _OTC

CHEMICAL NAME, CHEMICAL STRUCTURE, MOLECULAR FORMULA, AND MOLECULAR WEIGHT:

Amoxicillin Trihydrate $C_{15}H_{19}N_3O_5S.3H_2O$ & Clavulanate Potassium $C_8H_8KNO_5$
(2S,5R,6R)-6-[(R)-(-)-2-amino-2-(p-hydroxyphenyl)acetamido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0] heptane-2-carboxylic acid trihydrate
Amoxicillin trihydrate: CAS-61-336-70-7 M.W. 419.46



15. RELATED/SUPPORTING DOCUMENTS:

16. COMMENTS:

17. CONCLUSIONS AND RECOMMENDATIONS:

CBE-30 supplement SCE-021 of NDA 50-725 is recommended for approval.

CC:

HFD-520/Samanta
HFD-520/Chem/Yu
HFD-520/ChemTL/Vidra

WITHHOLD 2 PAGE(S)

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Chemistry Review

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/s/

Andy Yu
6/12/03 02:47:20 PM
CHEMIST

Jim Vidra
6/12/03 03:00:46 PM
CHEMIST

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APPLICATION NUMBER:

50-725 / S-021

ADMINISTRATIVE DOCUMENTS AND CORRESPONDENCE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-725/S-021

GlaxoSmithKline
Attention: David Desris, Pharm.D.
Assistant Director, Global Antibiotic CMC Regulatory Affairs
1250 South Collegeville Road
P. O. Box 5089
Collegeville, Pennsylvania 19426-0989

Dear Dr. Desris:

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product:	Augmentin® (amoxicillin/clavulanate potassium) Oral Suspension BID
NDA Number:	50-725
Supplement number:	S-021
Date of supplement:	December 13, 2002
Date of receipt:	December 16, 2002

This supplemental application, submitted as "Supplement - Changes Being Effected in 30 Days" extends the expiration date from 12 months to 18 months.

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on February 14, 2003, in accordance with 21 CFR 314.101(a).

All communications concerning this supplement should be addressed as follows:

U.S. Postal Service:
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anti-Infective Drug Products, HFD-520
Attention: Division Document Room
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anti-Infective Drug Products, HFD-520
Attention: Division Document Room
9201 Corporate Blvd.
Rockville, Maryland 20850-3202

If you have any question, call Susmita Samanta, Regulatory Project Manager, at (301) 827-2125.

Sincerely yours,

{See appended electronic signature page}

Frances LeSane
Chief, Project Management Staff
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

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/s/

Frances LeSane
1/15/03 06:29:28 PM