CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 50760

CHEMISTRY REVIEW(S)

DIVISION OF ANTI-INFECTIVE DRUG PRODUCTS
Review of Chemistry, Manufacturing, and Controls

NDA #: 50-760 **CHEM.REVIEW #:** 2 **REVIEW DATE:** 26-MAR-1999

SUBMISSION/TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
ORIGINAL	15-APR-98	16-APR-98	15-MAY-98
AMENDMENT (Stability)	19-JUN-98	22-JUN-98	26-JUN-98
AMENDMENT (Stability)	13-JAN-99	16-JAN-99	16-JAN-99
AMENDMENT (Stability)	23-MAR-99	25-MAR -99	25-MAR -99

NAME & ADDRESS OF APPLICANT:
SMITHKLINE BEECHAM PHARMACEUTICALS
One Franklin Plaza
P.O. Box 7929
Philadelphia, PA 19101-7929

DRUG PRODUCT NAME

Proprietary:	Amoxil Oral Suspension
Nonproprietary/USAN:	Amoxicillin Oral Suspension
Code Names/#'s:	
Chemical Type/ Therapeutic Class:	3 S

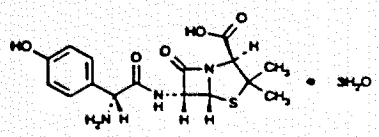
ANDA Suitability Petition/DESI/Patent Status: N/A
[if applicable]

PHARMACOLOGICAL CATEGORY/INDICATION: Anti-infective

DOSAGE FORM: powder for oral suspension
STRENGTHS: 200 mg and 400 mg per 5 mL

ROUTE OF ADMINISTRATION: oral
DISPENSED: X Rx __ OTC
CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOL.WT:

Amoxicillin Trihydrate $C_{15}H_{19}N_3O_5S.3H_2O$
(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
CAS-61-336-70-7
M.W. 419.46



SUPPORTING DOCUMENTS:

Amoxicillin trihydrate drug substance

No DMF authorization needed, the DMF's are held by the sponsor.
NDA 50-760 Review #1, 3/1/99

RELATED DOCUMENTS (if applicable)

USP 23 Page 100
USP 23 Page 102
Other related Amoxil NDAs
NDA 50-726 - chewable tablet, 200mg and 400 mg
NDA 50-564 - tablet, 250mg and 500 mg
NDA 50-575 - Oral suspension, 125 mg/5 mL and 250 mg/5 mL
NDA 50-725 - Oral suspension, 200 mg/5 mL and 400 mg/5 mL

For HDPE bottles, No DMF authorization is needed, the DMFs are held by the sponsor.

Other DMFs:
DMF
DMF
DMF
DMF
DMF
DMF
DMF
DMF

The firm has provided DMF authorization letters.

CONSULTS

A consult was sent to the Labeling and Nomenclature Committee and nomenclature was acceptable.

REMARKS/COMMENTS :

The [ ] facility is presently being inspected. All other manufacturing and control facilities were approved based on either profile or actual inspection.

CONCLUSIONS & RECOMMENDATIONS:

Recommend approval from the manufacturing and controls standpoint. All pending issues have been satisfactory resolved. All manufacturing facilities are currently in acceptable GMP compliance or pending [ ]

/S/

Andrew Yu, Review Chemist

cc: Orig. NDA 50-760
HFD-520
HFD-520/DivDir/J Soreth
HFD-520/Chem/AYu
HFD-520/MO/MMakhene
HFD-520/MAlbuerne
HFD-520/Pharm/ROsterberg
HFD-520/Micro/SAltaire
HFD-520/CSO/STrostle
R/D Init by: HFD-520/TmLdrChem/ DKatague DB/(3/24/99

DIVISION OF ANTI-INFECTIVE DRUG PRODUCTS
Review of Chemistry, Manufacturing, and Controls

NDA #: 50-760 **CHEM.REVIEW #:** 1 **REVIEW DATE:** 1-MAR-1999

SUBMISSION/TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
ORIGINAL	15-APR-98	16-APR-98	15-MAY-98
AMENDMENT (Stability)	19-JUN-98	22-JUN-98	26-JUN-98
AMENDMENT (Stability)	13-JAN-99	16-JAN-99	16-JAN-99

NAME & ADDRESS OF APPLICANT:
SMITHKLINE BEECHAM PHARMACEUTICALS
One Franklin Plaza
P.O. Box 7929
Philadelphia, PA 19101-7929

DRUG PRODUCT NAME

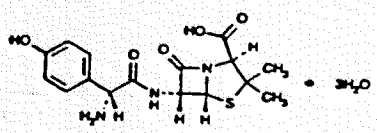
Proprietary:	Amoxil Oral Suspension
Nonproprietary/USAN:	Amoxicillin Oral Suspension
Code Names/#'s:	
Chemical Type/ Therapeutic Class:	3 S

ANDA Suitability Petition/DESI/Patent Status: N/A
[if applicable]

PHARMACOLOGICAL CATEGORY/INDICATION: Anti-infective

DOSAGE FORM: powder for oral suspension
STRENGTHS: 200 mg and 400 mg per 5 mL

ROUTE OF ADMINISTRATION: oral
DISPENSED: X Rx ___ OTC
CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOL.WT:



Amoxicillin Trihydrate $C_{15}H_{19}N_3O_5S.3H_2O$
(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
CAS-61-336-70-7
M.W. 419.46

SUPPORTING DOCUMENTS:

Amoxicillin trihydrate drug substance

No DMF authorization needed, the DMF's are held by the sponsor.

RELATED DOCUMENTS (if applicable)

USP 23 Page 100
USP 23 Page 102
Other related Amoxil NDAs
NDA 50-726 - chewable tablet, 200mg and 400 mg
NDA 50-564 - tablet, 250mg and 500 mg
NDA 50-575 - Oral suspension, 125 mg/5 mL and 250 mg/5 mL
NDA 50-725 - Oral suspension, 200 mg/5 mL and 400 mg/5 mL

For bottles, No DMF authorization is needed, the DMFs are held by the sponsor.

Other DMFs:
DMF
DMF
DMF
DMF
DMF
DMF
DMF
DMF

The firm has provided DMF authorization letters.

CONSULTS

A consult was sent to the Labeling and Nomenclature Committee and nomenclature was acceptable.

REMARKS/COMMENTS :

The facility is presently being inspected. All other manufacturing and control facilities were approved based on either profile or actual inspection.

CONCLUSIONS & RECOMMENDATIONS:

The application is **not** approvable for controls under section 505(b) of the Act. Specific items which are not approvable are identified under the following headings: Drug Products [Methods of manufacturing and packaging, Specification and Methods for Drug Product, Stability, and Labeling].

/S/ 3/1/99

Andrew Yu, Review Chemist

cc: Orig. NDA 50-760
HFD-520
HFD-520/DivDir/GChikami
HFD-520/Chem/AYu
HFD-520/MO/MMakhene
HFD-520/MAlbuerne
HFD-520/Pharm/ROsterberg
HFD-520/Micro/SAltaire
HFD-520/CSO/STrostle
R/D Init by: HFD-520/TmLdrChem/ DKatague DBK 3/2/99