CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-779

CHEMISTRY REVIEW(S)

APR 11 2000

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

NDA #: 50-779 **CHEM.REVIEW #:** 1 **REVIEW DATE:** 10-APR-1999

SUBMISSION/TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
ORIGINAL	23-AUG-99	25-AUG-99	30-AUG-99
AMENDMENT (Certificate of analysis)	27-OCT-99	28- OCT -99	28- OCT -99
AMENDMENT (Facility & PI)	19-JAN-00	20-JAN-00	27- JAN -00

NAME & ADDRESS OF APPLICANT:
B. Braun Medical Inc.
2525 McGaw Avenue
P.O. Box 19791
Irvine, CA 92623

DRUG PRODUCT NAME

Proprietary:	Cefazolin for injection and Dextrose injection in the Duplex™ container
Nonproprietary/USAN:	Cefazolin for injection USP and Dextrose injection USP.
Code Names/#'s:	
Chemical Type/ Therapeutic Class:	5 S

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

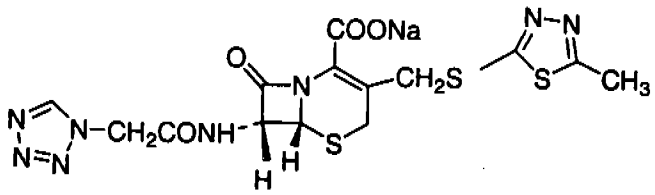
PHARMACOLOGICAL CATEGORY/INDICATION: Anti-infective

DOSAGE FORM: Sterile injection in bag
STRENGTHS: 500 mg and 1 gm bag

ROUTE OF ADMINISTRATION: Parenteral
DISPENSED: X Rx __ OTC
CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA,

B. Braun Medical Inc.

MOL.WT:



Cefazolin Sodium $C_{14}H_{13}N_8NaO_4S_3$
Sodium (6R,7R)-3-[[(5-methyl-1,3,4-thiadiazol-2-yl)thio]methyl]-8-oxo-7-[2-(1H-tetrazol-1-yl)acetamido]-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate
CAS-27164-46-1
M.W. 476.50

Dextrose USP $C_6H_{12}O_6H_2O$
D-Glucose Monohydrate
CAS-5996-10-1
M.W. 198.17

SUPPORTING DOCUMENTS:

Cefazolin Sodium drug substance (sterile lyophilized)

[redacted] issued to B. Braun Medical, Inc.

RELATED DOCUMENTS (if applicable)

USP 24 Page 329
USP 24 Page 329-330
Other related NDAs

[redacted]

B. Braun Medical Inc.

[redacted]

CONSULTS

A consult was sent to the Labeling and Nomenclature Committee and nomenclature was acceptable. A consult was sent to Microbiology for sterility and microbiological consult.

REMARKS/COMMENTS :

[redacted]

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/

Andrew Yu, Review Chemist

cc: Orig. NDA 50-779
HFD-520
HFD-520/DivDir/GChikami
HFD-520/Chem/AYu
HFD-520/MO/JAlexander
HFD-520/JSoreth
HFD-520/Pharm/ROsterberg
HFD-520/Micro/S Aitaie
HFD-520/CSO/Duvall-Miller
R/D Init by: HFD-520/TmLdrChem/ DKatague /S/ 4/11/00

51 page(s) have been removed because it contains trade secret and/or confidential information that is not disclosable.

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

NDA #: 50-779 **CHEM.REVIEW #:** 2 **REVIEW DATE:** 22-JUN-2000

SUBMISSION/TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
ORIGINAL	23-AUG-99	25-AUG-99	30-AUG-99
AMENDMENT (Certificate of analysis)	27-OCT-99	28- OCT -99	28- OCT -99
AMENDMENT (Facility & PI)	19-JAN-00	20-JAN-00	27- JAN -00
AMENDMENT (Stability data)	19- MAY -00	22- MAY -00	26- MAY -00

NAME & ADDRESS OF APPLICANT:
B. Braun Medical Inc.
2525 McGaw Avenue
P.O. Box 19791
Irvine, CA 92623

DRUG PRODUCT NAME

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Chemical Type/ Therapeutic Class:	5 S

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

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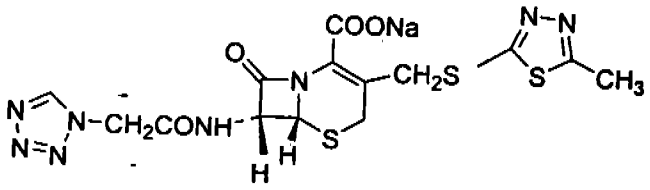
B. Braun Medical Inc.

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOL.WT:



Cefazolin Sodium $C_{14}H_{13}N_8NaO_4S_3$
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SUPPORTING DOCUMENTS:

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[redacted]

RELATED DOCUMENTS (if applicable)

USP 24 Page 329
USP 24 Page 329-330
Other related NDAs

[redacted]

[redacted]

CONSULTS

A label consult was sent to OPDRA and nomenclature was acceptable. A consult was sent to Microbiology for sterility and the microbiological review is attached.

REMARKS/COMMENTS :

[redacted]

CONCLUSIONS & RECOMMENDATIONS:

The application is approvable under section 505(b) of the Act. All deficiencies identified under CMC have been resolved except [redacted] which has been scheduled and expected to be completed in late June.

/S/

Andrew Yu, Review Chemist

cc: Orig. NDA 50-779
HFD-520
HFD-520/DivDir/GChikami
HFD-520/Chem/AYu
HFD-520/MO/JAlexander
HFD-520/JSoreth
HFD-520/Pharm/ROsterberg
HFD-520/Micro/ Attaie
HFD-520/CSO/Duvall-Miller
R/D Init by: HFD-520/TmLdrChem/ DKatague /S/ 6/22/00