CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
21-222

CHEMISTRY REVIEW(S)
DIVISION OF ANTI-INFECTIVE DRUG PRODUCTS
Review of Chemistry, Manufacturing, and Controls

#3
NDA #: 21-222 CHEM.REVIEW #: 1 REVIEW DATE: 15-Sept-2000

SUBMISSION/TYPEn DOCUMENT DATE CDER DATE ASIGNED DATE
AMENDMENT BC: 06/13/00 06/14/00 06/15/2000
Amendment BC: 7/12/00 7/13/00 7/20/00
(stability update)

NAME & ADDRESS OF APPLICANT:
Tap Holdings Inc.
2355 Waukegan Road
Deerfield, IL 60015

DRUG PRODUCT NAME
Proprietary: SPECTRACEF
Nonproprietary/USAN: Cefditoren pivoxil
Code Names/#'s: MF1207, A-CDTR, RCF, CDTR-Pl
Chemical Type/: Antibiotic
Therapeutic Class: IS

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

PHARMACOLOGICAL CATEGORY/INDICATION: Antibiotic
For the treatment of pharyngitis/tonsillitis; Acute exacerbations of chronic bronchitis.

DOSAGE FORM: Tablets
STRENGTHS: 200mg
ROUTE OF ADMINISTRATION: Oral
DISPENSED: X Rx ___ OTC

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA.
1. Name and chemical structure

1.1. Generic name
Cefditoren pivoxil

1.2. Chemical name
(-)-(6R, 7R)-2, 2-dimethylpropionyloxymethyl 7-[(Z)-2-(2-aminothiazol-4-yl)-2-methoxyiminoacetamido]-3-[(Z)-2-(4-methylthiazol-5-yl)ethenyl]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate

1.3. Abbreviation
CDTR-PI

1.4. Structural formula

1.5. Molecular formula
C_{25}H_{29}N_{6}O_{7}S_{3}

1.6. Molecular weight
620.73

SUPPORTING DOCUMENTS:
RELATD DOCUMENTS (if applicable):

None

CONSULTS:

1. METHOD VALIDATION: ADEQUATE

Both the Puerto Rico District Laboratory and the Philadelphia District Laboratory have found the methods acceptable for regulatory purposes.

2. INSPECTION: PENDING

All the facilities were found to be ACCEPTABLE as of July 13, 2000 except the following which was added by the firm recently by an amendment as an alternate packaging site:

- The firm claims that the above facility had a satisfactory GMP inspection on January 7, 2000. However, Dr. David Katague, in Dr. Shetty's absence (vacation) had requested to EES Question on July 20, 2000 to add the above facility to EER.

3. PROPRIETARY NAME: ADEQUATE

The name was found to be acceptable.

REMARKS/COMMENTS:
CONCLUSIONS & RECOMMENDATIONS:

Recommend approval; EER is ACCEPTABLE. See attached.

B.V. Shetty, Review Chemist

CC:
Orig. NDA 21-222
HFD-520/Division File
HFD-520/B.V. Shetty/date
HFD-520/J. Alexander
HFD-520/K. Seethaler
HFD-520/J. Unowsky
HFD-520/G. Hills
HFD-520/F. Pelsor
HFD-830/C. Chen
HFD-520/D. Katague
DIVISION OF ANTI-INFECTIVE DRUG PRODUCTS
Review of Chemistry, Manufacturing, and Controls

NDA #: 21-222  CHEM.REVIEW #: 2  REVIEW DATE: 10/17/2000

(Response to IR letter tele-faxed to applicant on September 20, 2000)

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Tap Holdings Inc.
2355 Waukegan Road
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DRUG PRODUCT NAME
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Nonproprietary/USAN: Cefditoren pivoxil
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Therapeutic Class: IS

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   620.73
SUPPORTING DOCUMENTS:

RELATED DOCUMENTS (if applicable):

NONE

CONSULTS:

NONE

REMARKS/COMMENTS:

The current submission is the firm's response to the IR letter tele-faxed on September 20, 2000, as outlined in Chemist Review #1 dated September 15, 2000.

CONCLUSIONS & RECOMMENDATIONS:

The applicant has satisfactorily has answered all the deficiencies stated in chemist review #1 dated September 15, 2000. NDA 21-222 is recommended for APPROVAL from CMC point of view, Method Validations, locality inspections and trade name have all been found to be ACCEPTABLE.

/\S/ 10/24/02

B.V. Shetty, Review Chemist
DIVISION OF ANTI-INFECTIVE DRUG PRODUCTS
Review of Chemistry, Manufacturing, and Controls

NDA #: 21-222   CHEM.REVIEW #: 3   REVIEW DATE: 6/22/01

SUBMISSION/TYPE   DOCUMENT DATE   CDER DATE   ASSIGNED DATE
Amendment BC:  7/12/00  7/13/00  7/20/00
(stability update)

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1.3. **Abbreviation**
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1.4. **Structural formula**

![Structural formula image]

1.5. **Molecular formula**
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**SUPPORTING DOCUMENTS:**
RELATED DOCUMENTS (if applicable):
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   PENDING

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3. PROPRIETARY NAME:
   ADEQUATE

   The name was found to be acceptable.
REMARKS/COMMENTS:

CONCLUSIONS & RECOMMENDATIONS:
APPROVABLE
Recommend to approve this NDA.; ZER is ACCEPTABLE. See attached.

B.V. Shetty, Review Chemist

CC:
Orig. NDA 21-222
HFD-520/Division File
HFD-520/B.V. Shetty/date
HFD-520/J. Alexander
HFD-520/K. Seethaler
HFD-520/J. Unowsky
HFD-520/G. Hills
HFD-520/F. Pelsor
HFD-830/C. Chen