

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-130/S-003

21-131/S-003

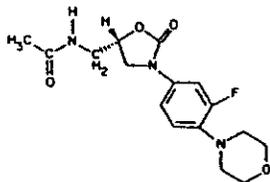
21-132/S-003

CHEMISTRY REVIEW(S)

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

1. **NDA NUMBER/SUPPLEMENT:** 21-130/SE5-003
 2. **REVIEW:** # 1
 3. **REVIEW DATE(s):** 12/13/02; **LETTER DATE:** 6/21/02
 4. **STAMP DATE:** 6/24/02; **DUE DATE:** 12/24/02
 5. **SUPPLEMENT PROVIDES FOR:** This is an efficacy supplement to meet the requirements of the Pediatric Rule with a claim for a categorical exclusion to the environmental assessment requirements in accordance with 21 CFR 25.31(b).
 6. **PREVIOUS DOCUMENTS:** None
 7. **SUBMISSION(S) BEING REVIEWED:** BC Amendment 8/16/02
 8. **NAME AND ADDRESS OF APPLICANT**
Pharmacia & Upjohn
7000 Portage Road
Kalamazoo, MI 49001-0199
Contact: Robert Gremban (269)833-9195
 9. **DRUG PRODUCT NAME:**
Proprietary Name : Zyvox
Nonproprietary Name: Linezolid
 10. **PHARMACOLOGICAL CATEGORY:** Anti-infective
 11. **DOSAGE FORM:** Tablets
 12. **STRENGTH/POTENCY:** 400 mg and 600 mg.
 13. **ROUTE OF ADMINISTRATION:** Oral
 14. **Rx/OTC DISPENSED:** Rx OTC
- CHEMICAL NAME, CHEMICAL STRUCTURE, MOLECULAR FORMULA, and MOLECULAR WEIGHT:** N-[[[(S)-3-(3-Fluoro-4-morpholinophenyl)-2-oxo-5-oxazolidinyl]methyl]acetamide.

C₁₆H₂₀FN₃O₄, MW: 337.35



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15. RELATED/SUPPORTING DOCUMENTS: Bundled with NDA 21-131 SE5-003 and 21-132 SE5-003.

16. COMMENTS: The electronic archival copy of the amendment to this supplement was reviewed which is a chemistry amendment for an EA categorical exclusion.

17. CONCLUSIONS AND RECOMMENDATIONS: The information is adequate to claim categorical exclusion for environmental assessment requirements.

CC Hard Copy:

HFD-520/Duvalmiller

HFD-830/Dunn

HFD-520/Pagay

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ASSESSMENT:**Environmental Assessment : Adequate**

The applicant has claimed that the total planned production of the drug substance is estimated to be at levels where the aquatic concentration is estimated to be below the concentration of 1 part per billion (ppb). The sponsor claims that at this level they are not aware of any toxic effect to microorganisms in the environment.

Reviewer's comment: According to the CMC review of the original NDA, the environmental assessment was waived based on the amount projected to be introduced in the environment to be below 1 ppb as per guidance (item II page 2 in the guidance for "Environmental Assessment of Human Drug and Biologics Applications issued 7/1998). If the planned production volume is to be at levels below 1 ppb, the claim of categorical exclusion is acceptable

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/s/

Shrikant Pagay
12/16/02 05:32:11 PM
CHEMIST

Bonnie Dunn
12/16/02 05:49:36 PM
CHEMIST

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