

**CENTER FOR DRUG EVALUATION AND RESEARCH**

*APPLICATION NUMBER:*

**17-430/S-026, S-027**

**MEDICAL REVIEW**



Reviewer's Comment: *The sponsor has chosen not to include a dose selection statement since they do not recommend a dose range for this product as there is concern that underdosing may encourage bacterial resistance. This is acceptable.*

The proposed Geriatric Use subsection continues with:

[ ]

Reviewer's Comment: *The wording of this statement should be replaced by that which is included in the Federal Register Notice:*

"This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function."

**Recommendations:** The applicant should be requested to submit an amendment to this supplement modifying their proposed "Geriatric Use" subsection as recommended above. With such a modification, the proposed Labeling Supplement may be approved.

Concurrence:

HFD-590 Division Director: Goldberger, M.

HFD-590 Deputy Division Director: Albrecht, R.

2/18/79

CC:

HFD-590 Division Files

NDA-14-214

NDA-17-430

HFD-590 chemistry: Schmuff

HFD-590 pharmtox: Hastings

HFD-590 micro: Dionne

HFD-590 biopharm: Ajayi

HFD-590 CSO: R. Anderson

**APPEARS THIS WAY  
ON ORIGINAL**