

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-784 / S-004, S-006

CHEMISTRY REVIEW(S)

Categorical Exclusion granted for the Drug Substance until 2005. See Memo included in this action book.

**APPEARS THIS WAY
ON ORIGINAL**

2/16/01

pages 26-30. The specifications and methods are acceptable.

Environmental Assessments: Adequate

A full environmental assessment package is included in page 50-59, Volume 4 of this supplement. Additional references were also made to the approved NDA 50-670 for further EA information. The present efficacy supplement is for pediatric use. According to the Memo dated 12/15/98 from Nancy Sager on pediatric supplements: Environmental Assessments/pediatric supplements:

"If the previously approved labeling *specifically restricted* use in a pediatric patient population, and it is now being added/expanded, then an EA would be needed. This is no longer current. Under the old regulations these always required EAs. However, under the Aug 97 regulations not all such actions would require an EA (depends on other things like how much active drug they are using for their product line)".

A categorical exclusion under 21 CFR § 25.31(b) is applicable in this case. The applicant referenced NDA 50-670 that it has no knowledge that any extraordinary circumstances exist. There is no information that indicates (e.g., use of wild plants/animals as a biomass source) that additional environmental information is warranted. References to EA in NDA 50-670 and an updated EA assessment was attached in this application (Appendix 1-4, Volume 4). The projected total use of Azithromycin is listed up to 2005. The proposed accelerated dosing for pediatric devices is not anticipated to result in an increased usage of POS (powder for oral suspension), but rather maintain the current usage as an approaching mature product. EIC was estimated at 1.97×10^{-03} mg/L assuming the worst case of R=)% or no sorption or degradation (P58, Volume 4).