CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20221/S012

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW	1. ORGANIZATION HFD-150 DODP	2. NDA NUMBER 20-221

3. NAME AND ADDRESS OF APPLICANT *(City and State)*
U.S. Bioscience, Inc.
One Tower Bridge
100 Front Street, Suite 400
West Conshochocken, PA 19428

4. AF NUMBER

5. SUPPLEMENT NUMBER / DATES

6. NAME OF DRUG	7. NONPROPRIETARY NAME		
Ethyol® for Injection	amifostine for injection	SE_1-012	23-DEC-1998

8. SUPPLEMENT PROVIDES FOR:
use of Ethyol to reduce the incidence and severity of radiation induced xerostomia. This review covers: (1) the claim of Categorical Exclusion under 21 CFR 25.31(b) from the requirement to prepare an Environmental Assessment and (2) applicable parts of the labeling.

9. AMENDMENTS DATES

10. PHARMACOLOGICAL CATEGORY	11. HOW DISPENSED	12. RELATED IND/NDA/DMF
chemoprotective agent	RX xx OTC __	
13. DOSAGE FORM(S)	14. POTENCY	
sterile lyophilized powder for injection	500 mg/vial	

15. CHEMICAL NAME AND STRUCTURE
2-[(3-aminopropyl)amino]ethanethiol dihydrogen phosphate (ester)

$H_2N(CH_2)_3NH(CH_2)_2S\text{-}PO_3H$ MW = 214.23 $C_5H_{15}N_2O_3PS$

16. RECORDS AND REPORTS
CURRENT YES__NO
REVIEWED YES_NO

17. COMMENTS

Cc: Orig. NDA 20-221
HFD-150/Div File
HFD-150/RPBarron
HFD-150/Mpelosi
R/D initial by /S/ 6-1-99

18. CONCLUSIONS AND RECOMMENDATIONS

Based on the amount of less than 1 ppb of the active moiety, amifostine, as the estimated concentration at the point of entry in the aquatic environment, the supplement qualifies for a categorical exclusion under CFR 25.31(b). The preparation of an environmental assessment or environmental impact statement is therefore not required. Approval of the supplement with regard to the environmental assessment requirements is recommended. Orphan designation was granted for this new indication in letter dated 12-MAY-1998 from the FDA Office of Orphan Products Development. The chemical name in the PI should revised to the univerted name.

19. REVIEWER NAME	SIGNATURE	DATE COMPLETED
Robert P. Barron	/S/	5/28/99

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