NDA-19-125

S-028

NDA 19-125/S-028

Mr. Richard P. Spiller
Vice President, Regulatory Affairs
Xttrium Laboratories
415 W. Pershing Rd.
Chicago, Illinois 60609

Dear Mr. Spiller:

Please refer to your supplemental New Drug Application (NDA) dated April 26, 1996, submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Exidine (chlorhexidine gluconate) Topical Solution. 4%.

The supplemental application provide for the release of the reprocessed batch 512-1061-976.

We have completed our review of this supplemental application and it is approved effective as of the date of this letter.

Please submit to the file your report on the investigation of the reason/s for the failure and the corrective action/s you have implemented.

We acknowledge your commitment to place the lot of the marketed batch on stability and submit the results via annual reports.

This approval affects only those changes specifically submitted in this supplemental application. Other changes that may have been approved or are pending evaluation are not affected.

We remind you that you must comply with the requirements set forth under 21 CFR 314.80 and 314.81 for an approved NDA.

Sincerely yours,

6/6/96

Suva B. Roy, Ph.D.
Team Leader, DNDC III
Division of Anti-infective Drug Products (HFD-520)
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

cc:Orig NDA 19-125/S-028
HFD-82
HFD-473
HFD-520
HFD-735
HFD-730
HFD-104
HFD-638
HFC-130/JAllen
HFD-520/DivDir/MFanning
HFD-520/MO/Bostwick
HFD-520/CSO/Dillon-Parker
HFD-520/MICRO/Sheldon
HFD-830/CHEM/Timper
HFD-830/SBRoy:R/D initialed

NDA SUPPLEMENT REVIEW JUN - 6 1996

CHEMIST'S REVIEW | 1. **ORGANIZATION** | 2. **NDA NUMBER**
Review #1 | DAIDP (HFD-520) | 19-125

3. **NAME & ADDRESS OF APPLICANT**
Xttrium Laboratories
415 W. Pershing Rd.
Chicago, IL 60609
(312) 268-5800

4. **AF NUMBER**

5. **SUPPLEMENT NUMBER, DATE**
SCS-028, 4/26/96

6. **NAME OF DRUG**
Exidine

7. **NONPROPRIETARY NAME**
chlorhexidine gluconate

8. **SUPPLEMENT(s) PROVIDES FOR:**

9. **AMENDMENTS AND OTHER**
n/a

SCS-028: The supplemental application provides release of the batch for reprocessing Lot 512-1061-976, chlorhexidine gluconate solution that was subsequently increased to a Lot R512-1061-976. The reason for the reprocessing was high content of in the formulation.

10. **PHARMACOLOGICAL CATEGORY**
Antibacterial

11. **HOW DISPENSED**
Rx XXX OTC

12. **RELATED IND/NDA/DMF(s)**

13. **DOSAGE FORM(s)**
4% Topical Solution

14. **POTENCY(ies)**

15. **CHEMICAL NAME AND STRUCTURE**
CAS-3697-42-5; $C_{22}H_{30}Cl_2N_{10} \cdot 2C_6H_{12}O_7$, 897.77

16. **RECORDS AND REPORTS**

	CURRENT	REVIEWED
Yes	X	X
No		

17. **COMMENTS** n/a
Expedited review status was granted 6/6/96, S. Roy. The approval letter requests a follow-up report to be submitted to report corrective procedures, if necessary, to address the overage of isopropyl alcohol.

18. **CONCLUSIONS AND RECOMMENDATIONS**
Recommend approval of this supplement.

cc: Orig: NDA 19-125
HFD-520 HFD-520/Bostwick/MO
HFD-520/Sheldon/Micro HFD-520/Dillon-Parker/CSO
HFD-520/JTimper HFD-520/SBRoys:R/D initialed 6/6/96

19. **REVIEWER**

NAME	**SIGNATURE**	**DATE COMPLETED**
J.Timper	6/6/96	6/6/96

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