APPLICATION NUMBER: NDA 5970/S28

CHEMISTRY REVIEW(S)
see page 2.

cc: NDA 5-970
HFN-160, Doc Room 160
R/D PSTewart, 2/11/87
R/D init. GPoochikian, 2/19/87

18. CONCLUSIONS AND RECOMMENDATIONS

The application is approvable pending receipt of revised label.

FEB 26 1987

Initialled per GPoochikian, 2/19/87
**CHEMIST'S REVIEW**

**3. NAME AND ADDRESS OF APPLICANT (City and State):**
Elkins - Sinn Inc.
Cherry Hill, New Jersey 08034

**6. NAME OF DRUG:**
Sotradecol Injection

**7. NONPROPRIETARY NAME:**
Sodium Tetradecyl Sulfate Injection

**8. SUPPLEMENT(S) PROVIDES FOR:**
Responses to FDA letter dated 6/18/84 concerning S-027 and PR-021.

**10. PHARMACOLOGICAL CATEGORY:**
Sclerosing Agent

**13. DOSAGE FORM(S):**
Injection (intravenously)

**16. RECORDS AND REPORTS CURRENT**

**17. COMMENTS:**
S-027 RC responds to FDA letter dated 6/18/84.
S-028 PD responds to FDA letter dated 6/18/84 concerning PR-021.

cc: /NDA 5970
HFN-160, Doc Room 160
R/D GPoochikian, 5/28/85
R/D init. CPHoiberg, 5/30/85

**18. CONCLUSIONS AND RECOMMENDATIONS:**
Approval letter is recommended. However, it is recommended that the word be part of the product name to comply with the USP format.

Initialed per CPHoiberg, 5/30/85
<table>
<thead>
<tr>
<th><strong>1. ORGANIZATION</strong></th>
<th>HFN-160</th>
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<tbody>
<tr>
<td><strong>2. NDA NUMBER</strong></td>
<td>5-970</td>
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</tbody>
</table>
| **3. NAME AND ADDRESS OF APPLICANT (Chy and State)** | Elkins-Sinn, Inc.  
Cherry Hill, NJ 08034 |
| **4. AF NUMBER**    |         |
| **5. SUPPLEMENT(S) NUMBER(SI) DATE(SI)** | S-028  2/13/85  
S-030  8/22/86  
S-031  8/22/86 |
| **6. NAME OF DRUG** | Sotradecol Injection |
| **7. NONPROPRIETARY NAME** | Sodium tetradecyl sulfate injection. |
| **8. SUPPLEMENT(S) PROVIDES FOR:** | S-028 Labeling Revision  
S-030 Raising pH upper limit  
S-031 as alternate manufacturer |
| **9. AMENDMENTS AND OTHER REPORTS, ETC. DATES** | S-028 BL  
S-030 BC 2/12/87  
S-031 BC |
| **10. PHARMACOLOGICAL CATEGORY** | Sclerosing Agent |
| **11. HOW DISPENSED** | RX  
OTC |
| **13. DOSAGE FORM(S)** | Intravenous Injection |
| **14. POTENCY (Ieq)** | 1% and 3% |
| **15. CHEMICAL NAME AND STRUCTURE** | CH₃OSO₃Na  
C₁₂H₂₅ |
| | CH₃-CH-CH₂-CH-(CH₃)₂-CH-(CH₃)₃-CH₃ |
| | 7-ethyl-2-methyl-4-rhodeconl-sulfate sodium salt |
| **17. COMMENTS** | As requested, the label has been revised to add the word generic name. |
| **cc:** | NDA 5-970  
HFN-160, Doc Room 160  
R/D PStewart, 2/19/87  
R/D init. GPoochikian, 2/19/87 |
| **18. CONCLUSIONS AND RECOMMENDATIONS** | These supplements can be approved from a chemistry standpoint. The CSO should check the FPL to see that it agrees with the revised draft label.  
Initialed per GPoochikian, 2/19/87 |
| **FEB 26 1987** |         |
| **19. REVIEWER** | Patricia Stewart  
SIGNATURE  
DATE COMPLETED 2/19/87 |
| **DISTRIBUTION** | ORIGINAL JACKET  
REVIEWER  
DIVISION FILE |

FORM FDH 2266 (7/73)  
PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED.