

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER: NDA 5970/S13**

**CHEMISTRY REVIEW(S)**

<b>CHEMIST'S REVIEW</b> <small>(If necessary, continue any item on 8" x 10 1/2" paper. Key continuation to item by number.)</small>		<b>1. ORGANIZATION</b> OSE-DSDDP	<b>2. NDA NUMBER</b> 5-970						
<b>3. NAME AND ADDRESS OF APPLICANT (City and State)</b> Elkins - Linn, Incorporated Cherry Hill, New Jersey 08002		<b>4. DATE NDA APPROVED</b> 8/13/76	<b>5. IF PRIOR TO OCT 10, 1962. DATE APPROVED FOR EFFICACY</b>						
<b>6. NAME OF DRUG</b> Sotradecol	<b>7. NON-PROPRIETARY NAME</b> sodium tetradecyl sulfate	<b>8. SUPPLEMENT</b> <table border="1"> <tr> <td><b>NUMBER</b></td> <td><b>DATE</b></td> </tr> <tr> <td>5-070</td> <td>June 5, 1972</td> </tr> <tr> <td>5-013</td> <td>May 10, 1972</td> </tr> </table>		<b>NUMBER</b>	<b>DATE</b>	5-070	June 5, 1972	5-013	May 10, 1972
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5-070	June 5, 1972								
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<b>9. PURPOSE OF SUPPLEMENT</b> FPL which complies with FR of July 30, 1970 and includes labeling for new 2cc ampul		<b>10. AMENDMENT DATE(s)</b> June 30, 1972							
<b>12. PHARMACOLOGICAL CATEGORY</b> sclerosing agent		<b>11. OTHER DATE (Report, etc.)</b> R1 6/6/72							
<b>14. DOSAGE FORM</b> injection solution		<b>13. AF NUMBER</b> 32-080							
<b>15. HOW DISPENSED</b> <input checked="" type="checkbox"/> Rx <input type="checkbox"/> OTC		<b>16. RELATED IND/NDA/MF(s)</b>							
<b>17. POTENCY (mg)</b> 1070 and 370	<b>18. NAS/NRC</b> <input type="checkbox"/> UNDER REVIEW <input checked="" type="checkbox"/> REVIEWED July 30, 1970								
<b>19. CHEMICAL NAME</b>	<b>20. RECORDS AND REPORTS</b> <table border="1"> <tr> <td><b>CURRENT</b></td> <td><b>REVIEWED</b></td> </tr> <tr> <td><input checked="" type="checkbox"/> YES      <input type="checkbox"/> NO</td> <td><input checked="" type="checkbox"/> YES      <input type="checkbox"/> NO</td> </tr> </table>			<b>CURRENT</b>	<b>REVIEWED</b>	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO		
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<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO								
<b>21. CHEMICAL FORMULA</b>									
<b>22. REMARKS</b> Labeling is identical to draft copy with exception of addition of 2 mc ampul - found approvable 8/14/70.									
<b>23. CONCLUSIONS</b> "Approve" this application for efficacy.									
<b>24. NAME</b> [Signature]		<b>REVIEWER</b> [Signature]							
<b>DISTRIBUTION</b>		<b>DATE COMPLETED</b> Aug 28, 1972							
<input type="checkbox"/> ORIGINAL JACKET		<input type="checkbox"/> DUPLICATE JACKET							
<input type="checkbox"/> REVIEWER		<input type="checkbox"/> REVIEWER							