

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

19-452/S017

CHEMISTRY REVIEW(S)

NDA SUPPLEMENT REVIEW

CHEMIST'S REVIEW	1. ORGANIZATION DDDDP (HFD-540)	2. NDA NUMBER 19-452
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3. NAME & ADDRESS OF APPLICANT	4. AF NUMBER
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Hill Dermaceuticals, Inc.
Attention: Rosario G. Ramirez, MD
Director, Medical and Regulatory Affairs
2650 South Mellonville Avenue
Sanford, Florida 32773

5. SUPPLEMENT(s)
NUMBER(s)DATE(s)
(SE5) N 19-452/S017
dated 10/9/00

6. NAME OF DRUG Derma-Smooth/FS	7. NONPROPRIETARY NAME fluocinolone acetonide
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8. SUPPLEMENT(s) PROVIDES FOR:	9. AMENDMENTS AND OTHER (REPORTS, etc.) DATES S/A dated 7/27/01 & 8/31/01
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SE5- Provides for revised labeling to include the pediatric population of 2 years and older.

10. PHARMACOLOGICAL
Anti-inflammatory Agent

11. HOW DISPENSED
xxx Rx OTC

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

13. DOSAGE FORM(s)	14. POTENCY(ies)
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Topical Oil

0.05%

Environmental Impact:

Acceptable

The firm requested a categorical exclusion per 21 CFR 25.31(a) since the estimated concentration of active moiety into the aquatic environment is well below 1 part per billion (ppb). In support of this claim, the calculation of the EIC was submitted in amendment dated 8 /31/01.
information:

18. CONCLUSIONS AND RECOMMENDATIONS

Recommend approval letter to issue for this supplement. The PM should convey the following information as requested under items (1) and (2) above.

cc: Orig: NDA 19-452

- HFD-540
- HFD-540/KO
- HFD-540/Hill
- HFD-540/Wright
- HFD-540/EGPappas
- HFD-540/WHDeCamp:R/D initialed __

19. REVIEWER		
NAME	SIGNATURE	DATE COMPLETED
Ernest G. Pappas		09/25/01

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