

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20-769

ADMINISTRATIVE DOCUMENTS

PEDIATRIC PAGE

(Complete for all original applications and all efficacy supplements)

NDA/PLA # 20-789 Supplement # _____ Circle one: SE1 SE2 SE3 SE4 SE5 SE6

HFD-540 Trade (generic) name/dosage form: Locoid (hydrocortisone butyrate) Action: AP AE NA
Lipo cream

Applicant Inverusk Research Therapeutic Class Corticosteroid

Indication(s) previously approved 1-Relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.
2-Relief of inflammatory and pruritic manifestations of seborrheic dermatitis (Soluh).

Pediatric labeling of approved indication(s) is adequate _____ inadequate _____

Indication in this application Relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.
(For supplements, answer the following questions in relation to the proposed indication.)

1. **PEDIATRIC LABELING IS ADEQUATE.** Appropriate information has been submitted in this or previous applications and has been adequately summarized in the labeling to permit satisfactory labeling for all pediatric subgroups. Further information is not required.
2. **PEDIATRIC STUDIES ARE NEEDED.** There is potential for use in children, and further information is required to permit adequate labeling for this use. (See back)
- a. A new dosing formation is needed, and applicant has agreed to provide the appropriate formulation.
- b. The applicant has committed to doing such studies as will be required.
- (1) Studies are ongoing,
- (2) Protocols were submitted and approved.
- (3) Protocols were submitted and are under review.
- (4) If no protocol has been submitted, explain the status of discussions on the back of this form.
- c. If the sponsor is not willing to do pediatric studies, attach copies of FDA's written request that such studies be done and of the sponsor's written response to that request.
3. **PEDIATRIC STUDIES ARE NOT NEEDED.** The drug/biologic product has little potential for use in children. Explain, on the back of this form, why pediatric studies are not needed.
4. **EXPLAIN.** If none of the above apply, explain, as necessary, on the back of this form.

EXPLAIN, AS NECESSARY, ANY OF THE FOREGOING ITEMS ON THE BACK OF THIS FORM.

Signature of Preparer and Title (PM, CSO, MO, other)

Date

8/4/97

cc: Orig NDA/PLA # 20-789
HFD-540 /Div File
NDA/PLA Action Package
HFD-510/GTroendle (plus, for CDER APs and AEs, copy of action letter and labeling)

NOTE: A new Pediatric Page must be completed at the time of each action even though one was prepared at the time of the last action.

) Locoid Lipocream

The sponsor has not been requested to submit pediatric studies, but we are requesting that the label bear the statement that the safety and effectiveness in children have not been established, thus precluding the use in children.

)

)

Elisabethhof 19
P.O. Box 108
2350 AC Leiderdorp
The Netherlands
Telephone +(0)71 - 45 57 45
Fax +(0)71 - 45 58 00

Direct line -(0)71 - 455 - 882

Direct fax -(0)71 - 455 - 840

Our ref.

Your ref.

Date June 21, 1996

DEBARMENT CERTIFICATION

The applicant of this New Drug Application certifies that no persons who have been debarred by the FDA, pursuant to sections 306(a) and (b) of the U.S. Federal Food, Drug and Cosmetic Act, have been involved in any way with any of the tests (clinical or nonclinical) described in this Application. No debarred person has been involved in any way with any of the operations of this Application, nor with the preparation of this Application.

Dr. A.P. Morgenstern
(Signed)

Director Regulatory Affairs
(Title)

13.0 PATENT INFORMATION

This Section is not applicable to this NDA for Locoid Lipocream[®].

14.0 PATENT CERTIFICATION

This Section is not applicable to this NDA for Locoid Lipocream®.