CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 20-508/S005

CHEMISTRY REVIEW(S)

/SA Turujman

NOV 5 1999

DIVISION OF DERMATOLOGICAL AND DENTAL DRUG PRODUCTS
HFD-540

Review of Chemistry, Manufacturing, and Controls

NDA #: 20-508	CHEM. REVIEW #: 1	REVIEW DATE: 12-OCT-1999	
SUBMISSION/TYPE	**DOCUMENT DATE**	**CDER DATE**	**ASSIGNED DATE**
SUPPLEMENT/SE8	24-AUG-1999	26-AUG-1999	10-SEP-1999

NAME & ADDRESS OF APPLICANT: Westwood-Squibb
100 Forest Avenue
Buffalo, New York 14213-1091

Kathy B. Schrode, Ph.D.
Director, Worldwide Regulatory Affairs
(716) 887-7680
(716) 887-3638

DRUG PRODUCT NAME

Proprietary:	Lac-Hydrin cream
Nonproprietary/USAN:	Ammonium Lactate
Code Names/#'s:	None
Chemical Type/	3
Therapeutic Class:	S

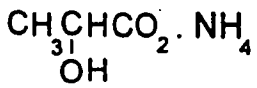
ANDA Suitability Petition/DESI/Patent Status:

PHARMACOLOGICAL CATEGORY/INDICATION: Ichthyosis Vulgaris, Xerosis

DOSAGE FORM:	Cream
STRENGTHS:	12%
ROUTE OF ADMINISTRATION:	Topical
DISPENSED:	X Rx ____ OTC

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOL. WT:

Racemic ammonium lactate



Molecular Formula:	$C_3H_9NO_3$
Molecular Weight:	109.11
CAS No.:	52003-58-4

SUPPORTING DOCUMENTS:

IND ——— Ammonium Lactate 12%, Bristol-Meyers Squibb Company; application is owned by the sponsor.

DMF —— Ammonium Lactate 12%, ——————— authorized by letter dated 8/29/94 (chemistry reviews dated 8/5/95 and 10/31/95).

DMF —— Type I (General Procedure), Westwood-Squibb Pharmaceuticals, Inc.; application is owned by the sponsor.

NDA 19,155, Lac-Hydrin lotion, 12%, Westwood-Squibb Pharmaceuticals, Inc. No letter of authorization is required since the applicant is the current holder of this DMF.

REMARKS/COMMENTS:

This is a prior approval labeling supplement which provides for revised labeling for pediatric use in accordance with 21 CFR 314.70(b)(3)(i). The sponsor provides a draft label and compares it with the one originally approved by FDA for NDA 20-508, and with the label which had been approved for a new packaging size (20-508/SCP-004, approved on 7/19/99).

Stability

This is an approved drug product without any change in formulation. No stability testing is required.

Label

The sponsor provides a three-column table which presents the current approved labeling in the first column, the proposed labeling which incorporates pediatric use in the second column, and the rationale for the proposed change in the third column. The proposed label is identical to the current label, except for the "Pediatric use" section. The new label states that "the safety and effectiveness of Lac-Hydrin cream have been established in pediatric patients as young as 2 years old". The appropriateness of this statement should be referred to the medical officer.

There are no other CMC issues in this submission.

CONCLUSIONS & RECOMMENDATIONS:

The supplemental application is recommended for APPROVAL under section 505(b) of the Federal Food, Drug, and Cosmetic Act.

/S/ 10/12/99
S. A. Turujman, Ph.D.
Reviewing Chemist

cc: Orig. NDA 20-508
HFD-540/Division File
HFD-540/DivDir/JKWilkin
HFD-540/ProjMan/KDWhite
HFD-540/Pharm/PBrown
HFD-540/MedOffr/DCook
HFD-540/Chem/SATurujman
HFD-540/TeamLdr/WHDeCamp

/S/ 11/5/99

filename:

for WHDeCamp