

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Application Number** 50-769

**MICROBIOLOGY REVIEW(S)**

NDA No. 50,769  
Product name Benzamycin®  
Company name Dermik Laboratories, Inc.

1 of 4

NOV 17 2000

**Division of Anti-Infective Drug Products**  
**Clinical Microbiological Review # 1**  
**Consult for the Division of Dermatologic and Dental Drug Products**

**NDA #50,769**

**Date Completed: November 1, 2000**

**Applicant: Dermik Laboratories Inc.**  
**500 Arcola Rd,**  
**Collegeville, Pa.**  
**19426-0107**

**Chem/Ther. Type: Antibiotic plus antiseptic**

**Submissions Reviewed: Original application, NDA**

**Providing for: Topical treatment of patients with Acne Vulgaris**

**APPEARS THIS WAY  
ON ORIGINAL**

**Product Name(s):**

**Proprietary: Benzamycin®**

**Non-proprietary/USAN: Erythromycin and Benzoylperoxide**

**Code name/number: DL-6026**

**Refer to USP dictionary of USAN and International Drug Names, 2,000-US  
Pharmacopoeia, pp. 87 and 274 for: Chemical name, Structural formula and,  
Molecular formula:**

**Dosage form: Gel to be mixed in a pouch, Erythromycin 3%, & Benzoyl Peroxide 5%.  
The pouch contains 0.8 gm of product.**

**Route of administration: Topical**

**Pharmacological Category: Antibiotic plus Antiseptic**

Product name Benzamycin®

Company name Dermik Laboratories, Inc.

Dispensed: Rx

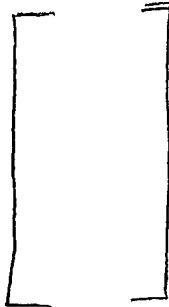
**Initial Submission Dates**

Received by CDER: 1-26-2000

Received by Reviewer: 4-18-2000

Review Completed: 10-30-00

**Related Documents:**



**APPEARS THIS WAY  
ON ORIGINAL**

**Remarks:**

Clinical microbiology data was not presented, nor were clinical microbiology studies conducted as part of this NDA.

Macrolide antibiotics (Erythromycin family) are also known to reduce inflammation and inhibit the formation of biofilms (not discussed by the applicant).

It would be interesting to document the incidence of overgrowth of nonsusceptible organisms with the marketed products, Erygel and Benzamycin including any differences in quality or quantity between the two products.

Peroxides are usually considered to be antiseptics rather than antibacterial agents.

**Conclusions/Recommendations:**

The formulary change from a gel to a gel to be created by mixing in a pouch should have no effect on the clinical microbiology of the product.

Therefore the product is recommended for approval.

Changes in the product package insert were discussed, negotiated and incorporated at a meeting held at 9201 corporate Blvd. Room S225 on November 1, 2000 with the division of Dermatology and Dental products, F. Cross and J. Wilkin presiding.

Product name Benzamycin®

Company name Dermik Laboratories, Inc.

1. The names of microorganisms were put in italics
2. Benzoyl peroxide is described as an oxidizing agent with antibacterial activity
3. The description of Pseudomembranous colitis was removed as the product is not absorbed.
4. Antibacterial activity as a mechanism of action of erythromycin in acne was removed.
5. The description of the mechanisms of action of erythromycin and benzoyl peroxide was listed as *invitro*.
6. It was pointed out that \_\_\_\_\_ is no longer a company and \_\_\_\_\_ is no longer a manufacturing site.
7. The anti-inflammatory and biofilm inhibitory properties of erythromycin were not incorporated into the label.

/S/

Joel Unowsky  
Microbiology Reviewer

Cc: Original NDA No. 50, 769

Smicro/ATSheldon

/S/ 12/00

DepDir/LGavrilovich

/S/ 14/00

HFD-520/SCSO/FLesane

Cc: Original NDA #50,769  
HFD-540/FCross

**APPEARS THIS WAY  
ON ORIGINAL**

12 Pages have been redacted in full  
from this document

Reason:

\_\_\_\_\_ b(2) 'low'

  X   b(4) CCI *DRAFT LABELING*

\_\_\_\_\_ b(4) TS

\_\_\_\_\_ b(5) Deliberative Process:

Attorney Client and Attorney Work  
Product Privilege

\_\_\_\_\_ b(6) Personal Privacy

\_\_\_\_\_ b(7) Law Enforcement Records