CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION:NDA 20-400

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Approval Package for:

Application Number: NDA 20-400

Trade Name:AVITA GEL, 0.025%

Generic Name:(tretinoin gel)

Sponsor:Penederm Incorporated

Approval Date: January 29, 1998

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number:NDA 20-400

APPROVAL LETTER

JAN 29 1998

NDA 20-400

Penederm Incorporated
Attention: John Quigley, Ph.D.
Senior Vice President, Research and Development
320 Lakeside Drive , Suite A
Foster City, CA 94404

Dear Dr. Quigley:

Please refer to your September 24, 1993, new drug application (NDA) and your resubmissions dated March 28, 1994, and July 12, 1996, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Avita™ (tretinoin gel) Gel, 0.025%.

Please refer to our not approvable letters dated March 29, 1995, June 26, 1996, and to our tentative approval letter dated January 14, 1997.

We acknowledge the receipt of your amendments and additional communications dated January 13 (two), 14, and 24, May 9, and October 28, 1997.

This new drug application provides for treatment of acne vulgaris.

We have completed the review of this application, including the submitted draft labeling, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed approved labeling text dated January 13, 1997. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed approved labeling text. Marketing the product with FPL that is not identical to this enclosed approved labeling text may render the product misbranded and an unapproved new drug.

Please submit twenty copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy weight paper or similar material. For administrative purposes this submission should be designated "FINAL PRINTED LABELING" for approved NDA 20-400. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of this drug become available, revision of that labeling may be required.

We remind you of your Phase 4 commitments specified in your submissions dated January 13 and 14, 1997. These commitments, along with any completion dates agreed upon, are listed below:

Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments must be clearly designated "Phase 4 Commitments."

In addition, please submit three copies of the introductory promotional material that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising, and Communications, HFD-40
5600 Fishers Lane
Rockville , Maryland 20857

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Please submit one market package of the drug when its available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Olga Cintron, R.Ph.
Consumer Safety Officer
(301) 827-2020

Sincerely yours,

1/29/98 /S/

Jonathan K. Wilkin, M.D.
Director
Division of Dermatologic and Dental
Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosure

cc:
Original NDA 20-400
HF-2/MedWatch (w/labeling)
HFD-2/MLumpkin (w/labeling)
HFD-92 (w/labeling)
HFD-105/OFFICE DIR/Weintraub (w/labeling)
HFD-540/DIV FILE (w/labeling)
HFD-540/CSO/Cintron (w/labeling)
HFD-540/MO/Labib (w/labeling)
HFD-830/CHEM/Timmer (w/labeling)
HFD-540/PHARM/Alam (w/labeling)
HFD-725/STAT/Farr (w/labeling)
HFD-880/BIOPHARM/Sun (w/labeling)
HFD-40 (w/labeling)
District Office (w/labeling)
HFD-613 (w/labeling)
HFD-735 (w/labeling)
HFD-005/Axelrad (w/labeling)

Concurrence:
HFD-540/PHARM TL/Jacobs (w/labeling)
HFD-830/CHEM TL/DeCamp (w/labeling)
HFD-540/SUPV PROJ MGR/Kozma-Fornaro (w/labeling) 1/21/98.
HFD-880/BIOPHARM TL/Bashaw (w/labeling)
HFD-160/MICRO TL/Cooney (w/labeling)
HFD-725/BIOSTAT TL/ Srinivasan (w/labeling)
HFD-540/ACTING CLINICAL TL/Toombs (w/labeling)
HFD-540/DIV DIR/Wilkin(w/labeling)

APPROVAL
PHASE 4 COMMITMENTS