MEMORANDUM 5742 '03 AUG 29 P2:43

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: August 28, 2003

FROM: Director
Division of OTC Drug Products (HFD-560)

SUBJECT: Public Administrative File for the Final Rule for Anorectal Drug Products for Over-the-Counter Human Use (Docket No. 80N-0050)

TO: Dockets Management Branch (HFD-305)

Under cover of this memorandum we are forwarding Volume No. 12FR3, to be added to the public administrative file for the Final Rule for Anorectal Drug Products for Over-the-Counter Human Use. The volume includes one new references cited in the final rule. References previously included in the public administrative file are not included with this memorandum. The attachment is to be placed on public display under Docket No. 80N-0050.

If there are any questions, the contact person on my staff is Gerald Rachanow, at 301-827-2307.

Charles J. Ganley, M.D.

Attachment

1980N-0050

BKG 1

PUBLIC ADMINISTRATIVE FILE

ANORECTAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE (DOCKET No. 80N-0050)

VOLUME 123R3

REFERENCES

1. Comment No. HER1.
2. LET 26.
3. Comment No. C25
4. OTC Vol. 123R3

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November 1, 1990

William E. Gilbertson, Pharm.D.
Director
Division of OTC Drug Evaluation
Office of Drug Standards
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857-1706

Re: Anorectal Drug Product
Docket No. 80N-0050, Comment No. HER1

Dear Dr. Gilbertson:

On September 17, 1990, on behalf of our client we received a request from the agency for additional information in support of the comments we filed on behalf of Ferndale Laboratories on December 13, 1988. You also stated that Ferndale Laboratories' comments filed in December, 1988 were being reviewed in conjunction with a filing to Federal Register Docket No. 88N-0242 (In the matter of Pramoxine Hydrochloride and Hydrocortisone Acetate Drug Products). For the sake of clarity, we have responded to the agency's request in the same format as the September 13, 1990 letter.

1. Fisher, Cutis, 25:584-591, 1980. Ferndale Laboratories is not in possession of any additional data beyond that filed in 1988. Any supporting data would be in Dr. Fisher's personal files, to which Ferndale does not have access. We, however, believe that the current data supports the effectiveness of the combination and hope that the agency will recognize its value when reviewing the article.

2. The Ferguson Clinic Study. On November 21, 1988, Ferndale Laboratories, along with Copley Pharmaceuticals, Parke-Davis, and Reed & Carnick, met with the agency in regard to hydrocortisone/pramoxine combination drug products. One of the matters discussed during the meeting was the protocol that

Ferndale had begun using at the Ferguson Clinic. Because of concerns expressed by the agency as to various parameters being measured in the study, it was agreed that further data collection would be suspended to give the agency an opportunity to review the protocol and offer constructive comments on the method and type of data that should be collected.

We have assumed that: (1) other matters before the agency are significantly impacting study design protocols; (2) the protocol submitted is still under current review; and (3) the agency will provide detailed comments which are to be considered for incorporation in our client's study design.

However, if the agency is not prepared to comment on the design, we can and will go forth with the study using the design presented at the November meeting. We have operated under the assumption that the agency would assist the scientific community, the public and Ferndale by providing comments on the study so that the results would provide definitive information on the combination of pramoxine and hydrocortisone.

I am taking the liberty of placing a copy of this letter in the docket files for both the OTC monograph and the notice of opportunity for hearing.

We would welcome a meeting to discuss the study design. I will be in contact with your office in the next few weeks to discuss this matter in greater detail.

Very truly yours,

Gary L. Yingling

GLY/lh