CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20-834

BIOEQUIVALENCE REVIEW(S)

AUG 22 1997

5% Minoxidil Topical Solution
Rogaine® Extra Strength For Men
NDA 20-834
Reviewer: E.D. Bashaw, Pharm.D.
APW

Pharmacia & UpJohn Co.
Kalamazoo, MI

Submission Date:
Feb. 28, 1997

Review of an Rx to OTC Switch

Background

UpJohn Pharmaceuticals, the fore-runner of Pharmacia-UpJohn, currently markets 2% minoxidil topical solution as an OTC product. It was originally approved under NDA 19-501 in 1988 for male pattern baldness (a/k/a androgenic alopecia). A supplement for use in women was approved in 1991 and a supplement for an Rx to OTC switch was approved in 1996. In 1996 a new NDA for a 5% topical solution was submitted by the applicant and subsequently found to be approvable in Dec. 1996 for male (but not female) androgenic alopecia. Late in the review of NDA the applicant attempted to change the indication of the NDA from an Rx to an OTC product. Because of the nature of this change it was decided by Agency management that this would require a separate NDA and the change in the pending NDA was not allowed. At this time the applicant has chosen not to pursue NDA to approval, but instead has chosen to file a new NDA for OTC use in male androgenic alopecia. In doing so the applicant has re-submitted all of the material originally contained in NDA to NDA 20-834 along with some additional clinical indications. No new pharmacokinetic information has been submitted.

Review History

The original pharmacokinetic review for the Rx 5% NDA was undertaken by Dr. Ahmed El-Tahtawy. In his review (dated 12/19/95) the pharmacokinetic portion of the Rx 5% product was found to be acceptable for marketing. Subsequent to his review appropriate labeling for this product, based on Dr. El-Tahtawy's review was developed by this reviewer. There are no outstanding pharmacokinetic phase IV requirements.

Current NDA

In filing this NDA the applicant has merely copied the pharmacokinetic portion of the Rx NDA and re-labeled it for the OTC indication. No new pharmacokinetic studies were undertaken to support the OTC indication for 5% minoxidil. Examination of the documentation submitted in this NDA and the material submitted in support of the Rx NDA have revealed no differences or discrepancies in the data submitted under either NDA. On the basis of the identical nature of the data submitted and the lack of influence of OTC vs. Rx marketing on the inherent pharmacokinetics of a drug, a new review of this material will not be undertaken at this time. As Dr. El-Tahtawy's review is still acceptable and as their are no outstanding pk review or pk-OTC specific issues, a formal review of this package will not be undertaken at this time.

Recommendation

As this NDA is merely a re-submission of the data that was previously reviewed in NDA and found to be acceptable, a formal review of this data (beyond checking for consistency between the NDA's) will not be performed. As there are no outstanding biopharmaceutic issues for this product, the product is acceptable from a biopharmaceutic standpoint for OTC marketing.

E. Dennis Bashaw, Pharm.D.
Senior Pharmacokineticist (HFD-550)
Division of Pharmaceutical Evaluation-III

Secondary Review, John Lazor, Pharm.D. 8/22/97

CC: NDA 20-834 (ORIG),
HFD-540/560/DIV File
HFD-540/CSO/Kozma-Fornaro
HFD-560/CSO/Wright
HFD-880(Bashaw)
HFD-880(Lazor)
CDR. ATTN: B. Murphy
HFD-344(Viswanathan)