JUL 29 1993

NDA 20-210

Janssen Research Foundation
Attention: Ms. Ruth Wasserman
1125 Trenton-Harbourton Road, P.O. Box 200
Titusville, NJ 08560-0200

Dear Ms. Wasserman:

Please refer to your August 29, 1991 new drug application submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Propulsid (cisapride) Tablets, 10 and 20 mg.

We also acknowledge receipt of your amendments dated April 27 and 30, May 21, June 18, July 1,12 and 14, 1993.

We have completed the review of this application, as amended, 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 revised draft labeling. Accordingly, the application, with these labeling revisions, is approved, effective as of the date of this letter.

These revisions are terms of the NDA approval. Marketing the product before making the revisions in the product's labeling may render the product misbranded and an unapproved new drug.

Please submit twelve copies of the FPL as soon as available. Seven of the copies should be individually mounted on heavy-weight paper or similar material. The submission should be designated for administrative purposes as "FPL for Approved NDA 20-210." Approval of the submission by FDA is not required before the labeling may be used.

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:

Kati Johnson
Consumer Safety Officer
(301) 443-0487

Sincerely yours,

R. Temple 7/29/93

Robert Temple, M.D.
Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure

M E M O R A N D U M

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

DATE: July 28, 1993

FROM: Director, Division of Gastrointestinal and Coagulation Drug Products, HFD-180

SUBJECT: Approval Action for Cisapride, NDA 20-210.

TO: Director, Office of Drug Evaluation I, HFD-100

An approval letter and the supporting documentation is transmitted for your consideration for Cisapride for the treatment of nocturnal heartburn.

We have commitments and the protocols for two additional clinical trials. The first will be a double-blind randomized placebo controlled study of 10 mg and 20 mg Q.I.D. of Cisapride in patients with GERD symptomatology. The second will evaluate either 10 or 20 mg 1/2 hour prior to and 3 hours following a provocative meal versus placebo to prevent or ameliorate symptoms of heartburn.

The safety update confirms our position that the drug has little associated toxicity, but we have added some information on tachycardia to the draft labeling. First, to the pharmacodynamic section we have included a statement on agonistic activity at the 5 HT_4 receptor that may result in tachycardia, and second to the adverse reaction section on positive rechallenge in some patients who experienced tachycardia.

We hope that we have provided sufficient information to you so that an approval action may be taken, but if you have any questions or concerns we will be happy to meet with you.

Stephen Fredd M.D.
Stephen Fredd, M.D.

cc: NDA 20-210
HFD-180
HFD-713/MHuque
HFD-713/ASankoh
Dr. Dubois
HFD-181/CSO/KJohnson
HFD-180/SFredd: 7/28/93
f/t deg: 7/28/93
MEMO\CISAPRID.2SF