

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 020623

CORRESPONDENCE

NDA 20-623

Johnson
SEP 22 1996

Hoechst Marion Roussel, Inc.
Attention: Louise Shibley
Marion Park Drive, P.O. Box 9707
Kansas City, MO 64134-0707

Dear Ms. Shibley:

We acknowledge receipt on September 13, 1996 of your September 12, 1996 amendment to your new drug application for Anzemet (dolasetron) Tablets.

We consider this a major amendment received by the agency within three months of the user fee due date. Therefore, the user fee clock is extended three months. The new due date is December 29, 1996.

If you have any questions, please contact:

Kati Johnson
Consumer Safety Officer
(301) 443-0487

Sincerely yours,

Stephen B. Fredd, M.D.
Director
Division of Gastrointestinal and Coagulation
Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

IS/ 9/27/96
IS/ 10/27/96

cc:
Original NDA 20-623
HFD-180/Div. Files
HFD-180/K.Johnson
DISTRICT OFFICE

drafted: kj/September 27, 1996/c:\wpfiles\cso\n\20623609.2kj
REVIEW EXTENSION

MEMORANDUM

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

DATE: October 12, 1995

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

SUBJECT: NDA 20,623 (ANZEMET/Dolasetron mesylate tablets) -
Deficiencies

TO: NDA 20,623

The following deficiencies are noted in the original submission. The assigned pharmacologist (Dr. Ahmad) may find additional deficiencies.

1. The table of contents of the application (volumes 1.1, 1.2 and 1.3) does not list the nonclinical studies with volume and page numbers. The indexing here refers to pagination in the summaries in volume numbers 1.22 and 1.23. The tables provided in the summaries need to be consulted to find the listing of individual studies.
2. Each application volume (volumes 1.22 to 1.58) lacks the display of table of contents of that volume. A search of volume by volume had to be undertaken to locate the beginning and end of each study. The displayed table of contents of each volume only refers to summaries in volumes 1.22 and volume 1.23.
3. No diskettes (studies format) for the tumor data in the mouse and rat carcinogenicity studies are provided.
4. No contemporary historical control data of tumor incidences of the testing laboratories for the mouse (volumes 1.29 to 1.33) and the rat (volumes 1.40 to 1.49) carcinogenicity studies could be located.

Sponsor should be asked to correct the aforementioned deficiencies expeditiously.

APPEARS THIS WAY
ON ORIGINAL

/S/

Jasti B. Choudary, Ph.D., B.V.Sc. *-10/12/95*

CC:
NDA
HFD-180
HFD-181/CSO
HFD-180/Dr. Ahmad
HFD-180/Dr. Choudary
HFD-180/Dr. Fredd

-Tofc for whole preclinical exn
-Tof 2 for @ volume

JBC/hw/10/12/95
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