CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: 020772

APPROVAL LETTER

NDA 20-772

APR - 9 1998

Orphan Medical, Inc.
Attention: Dayton Reardan, Ph.D.
13911 Ridgedale Drive
Minnetonka, MN 55305

Dear Dr. Reardan:

Please refer to your new drug application dated May 6, 1997, received May 7, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sucraid (sacrosidase) Oral Solution.

We acknowledge receipt of your submissions dated December 12, 1997, February 17 and March 13, 1998. The User Fee goal Date for this application is June 15, 1998.

This new drug application provides for Sucraid (sacrosidase) Oral Solution, 8,500 I.U./ml, packaged as two, 118 ml bottles, in the treatment of the genetically determined sucrase deficiency, which is part of congenital sucrase-isomaltase deficiency (CSID).

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the final printed labeling (package insert, patient package insert) submitted on December 12, 1997, and draft labeling (container and cartons) submitted on March 13, 1998. Accordingly, the application is approved effective on the date of this letter.

We remind you of the following Phase 4 commitments:

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. Should an IND not be required to meet your Phase 4 commitments, please submit protocol, data, and final reports to this NDA as correspondences.

In addition, we request under 21 CFR 314.81(b)(2)(vii) that you include in your annual report to this application, a status summary of each commitment. The status summary should include the number of patients entered in each study, expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments must be clearly designated "Phase 4 Commitments."

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.

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 Melodi McNeil, Regulatory Health Project Manager, at (301) 443-0483.

Sincerely yours,

/S/ 4/1/96

Paula Botstein, M.D.
Acting Director
Office of Drug Evaluation III
Center for Drug Evaluation and Research

APPEARS THIS WAY
ON ORIGINAL

cc:
Original NDA 20-772
HFD-180/Div. files
HFD-180/CSO/M.McNeil
HFD-180/Duffy
HFD-180/Shaw
HFD-180/Gallo-Torres
HFD-180/Choudary
HFD-720/Sankoh
HFD-870/Hunt
HFD-870/Chen
HFD-160/Hughes
HFD-46/Morris
HFD-002/ORM (with labeling)
HFD-103/Office Director
HFD-101/L.Carter
HFD-820/ONDC Division Director
DISTRICT OFFICE
HF-2/Medwatch (with labeling)
HFD-92/DDM-DIAB (with labeling)
HFD-40/DDMAC (with labeling)
HFD-613/OGD (with labeling)
HFD-735/DPE (with labeling) - for all NDAs and supplements for adverse reaction changes.
HFI-20/Press Office (with labeling)

/S/ 4-9-98
/S/ 4/9/98

Drafted by: mm/March 30, 1998/c:\wpfiles\cso\n\20772803.ap
Initialed by:
final:

APPROVAL (AP)

FINAL PRINTED LABELING HAS NOT BEEN SUBMITTED TO THE FDA.

DRAFT LABELING IS NO LONGER BEING SUPPLIED SO AS TO ENSURE ONLY CORRECT AND CURRENT INFORMATION IS DISSEMINATED TO THE PUBLIC.