

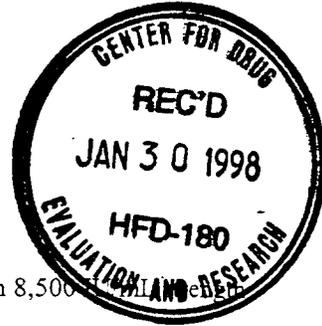
CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 020772

MICROBIOLOGY REVIEW(S)

REVIEW TO HFD-180
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGY REVIEW OF AN AMENDMENT # 1
JANUARY 27, 1998

- A. 1. **NDA 20-772**
APPLICANT: **Orphan Medical, Inc.**
13911 Ridgedale Drive, Suite 475
Minnetonka, MN 55305
2. Product Names: **Sucraid™**
Sacrosidase (USAN)
3. Dosage Form and Route of Administration: Liquid Oral Solution in 8,500
4. Sterilization Process:
5. Pharmacological Category: Oral enzyme replacement therapy for sucrase-isomaltase deficiency (CSID).
- B. 1. Date of Submission: December 12, 1997
2. Assigned for Review: December 12, 1997
3. Classification of Drug: 1/P
- C. **Remarks:** The amendment contains responses to microbiology information requests made to Orphan Medical, Inc. on July 31, 1997.
- D. **Conclusions:** The NDA 20-772 is recommended for approval from the standpoint of product quality microbiology.



IS/ 1/27/98
Patricia F. Hughes, Ph.D.
Microbiology Reviewer

cc.: Original NDA 20-772
HFD160-/Consult File
HFD-160/ PFHughes
HFD-180/Div Files
HFD-180/MMcNeil
HFD-180/Eduffy
HFD-180/AShaw
Drafted by PFHughes 01/27/98
R/D Initialed by PHCooney,

IS/ = 1/30/98

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REVIEW TO HFD-180
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW OF AN NDA
September 19, 1997

SEP 23 1997

SEP 23 1997

A. 1. NDA 20-772

PRODUCT NAME: Sucraid™ (sacrosidase) Oral Solution
Sacrosidase
beta-D-fructofurannoside fructohydrolase

APPLICANT: Orphan Medical, Inc.
13911 Ridgedale Drive, Suite 475
Minnetonka, MN 55305

- B. 1. DOSAGE FORM: Oral liquid formulation in strengths of 8,500 IU mL
2. METHOD(S) OF STERILIZATION:
3. PHARMACOLOGICAL CATEGORY PRINCIPAL INDICATION: Oral enzyme replacement therapy for the treatment of confirmed or suspected congenital sucrase-isomaltase deficiency.

- C. 1. INITIAL APPLICATION DATE: May 6, 1997
2. ASSIGNED FOR REVIEW: June 27, 1997
3. DATE OF AMENDMENT: September 12, 1997

APPROVED FOR REVIEW
BY: [Signature]

D. REMARKS: This NDA provides for the use of the drug product Sucraid™ for the orphan indication of the treatment of congenital sucrase-isomaltase deficiency (CSID). Sacrosidase, the active ingredient in Sucraid™ Oral Solution, is an enzyme that hydrolyzes sucrose to glucose and fructose. Sacrosidase is commercially available from _____ and is used in the food and candy industry.

E. CONCLUSIONS: The NDA 20-772 for Sucraid™ Oral Solution is not recommended for approval from the standpoint of microbiology.

/S/ — 9/19/97

cc.: Original NDA 20-722
HFD-160/Division File
HFD-160/PFHughes
HFD-180/MMcNeil
Drafted by PF Hughes, 09/19/97
R.D. Initialed by PH Cooney, 09/19/97

APPROVED FOR REVIEW
BY: [Signature]

Patricia F. Hughes, Ph.D.
Review Microbiologist

/S/ 9/19/97

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