

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER: 020772**

**CHEMISTRY REVIEW(S)**

DIVISION OF GASTROINTESTINAL AND  
COAGULATION DRUG PRODUCTS

MAR - 6 1998

Review of Chemistry, Manufacturing, and Controls

**NDA:# 20-772** CHEM REVIEW # 4 REVIEW DATE: February 4, 1998

<u>DOCUMENT TYPE</u>	<u>DATES</u>			<u>REV #</u>	<u>LETTER</u>	<u>DATE</u>
ORIGINAL	06-May-97	07-May-97	30-May-97	09-Sep-97	#1	
BC	01-Jul-97	02-Jul-97	09-Jul-97	09-Sep-97	#1	IR 07-Jul-97
BC	18-Jul-97	21-Jul-97	08-Aug-97	22-Sep-97	#2	
BC	20-Aug-97	22-Aug-97	05-Sep-97	22-Sep-97	#2	
BC	11-Sep-97	13-Sep-97	13-Sep-97	22-Sep-97	#2	IR 22-Sep-97
BL	25-Sep-97	26-Sep-97	06-Oct-97	08-Oct-97	#3	AE 06-Nov-97
AZ	12-Dec-97	15-Dec-97	22-Dec-97	Current		

NAME & ADDRESS OF APPLICANT:

Orphan Medical, Inc.  
13911 Ridgedale Drive, Suite 475  
Minnetonka, MN 55303

**BEST POSSIBLE COPY**

DRUG PRODUCT NAME:

Proprietary: Sucraid  
Nonproprietary/USAN: sacrosidase  
Code Name/#: Code  
Chem.Type/Ther.Class: 1P V

PHARMACOLOGICAL CATEGORY Enzyme replacement therapy

INDICATION: Oral replacement therapy for CSID

DOSAGE FORM: Liquid      STRENGTH: 8,500 IU/mL

ROUTE OF ADMINISTRATION: Oral

HOW DISPENSED:  Rx     OTC

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pages of trade

secret and/or

confidential

commercial

information

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NDA 20-772  
PAGE 4

RELATED DOCUMENTS: None

CONSULTS: Microbiology Acceptable Jan 30, 1998

REMARKS/COMMENTS: Most of the questions from our September 12, 1997 letter have been answered satisfactorily.

CONCLUSIONS & RECOMMENDATIONS: The application is approvable.

/S/

Arthur B. Shaw, Ph. D.  
Chemist, HFD-180

3/5/98

APPROVED FOR SIGNATURE

/S/

Eric P. Duffy, Ph.D.  
Chemistry Team Leader, HFD-180

3/6/98

cc:  
NDA 20-772  
HFD-180/Division File/NDA 20-772  
HFD-180/LTalarico  
HFD-820/JGibbs  
HFD-820/SKoepke  
HFD-180/EDuffy  
HFD-180/JChoudary  
HFD-181/MMcNeil  
R/D Init by:  
ABS/F/T abs 3/5/98 Wp #M:\WPFILES\20772802.5AS

APPROVED FOR SIGNATURE  
ON 3/5/98

OCT - 9 1997

**DIVISION OF GASTROINTESTINAL AND  
COAGULATION DRUG PRODUCTS**

Review of Chemistry, Manufacturing, and Controls

**NDA:# 20-772** CHEM REVIEW # 3 REVIEW DATE: October 8, 1997

<u>DOCUMENT TYPE</u>	<u>DATES</u>		<u>ASSIGNED</u>	<u>REVIEW</u>	<u>LETTER</u>	
	<u>DOCUMENT</u>	<u>CDER</u>				
ORIGINAL	06-May-97	07-May-97	30-May-97	09-Sep-97		Rev #1
Amendment	01-Jul-97	02-Jul-97	09-Jul-97	09-Sep-97		Rev #1
IR Letter					07-Jul-97	
Amendment	18-Jul-97	21-Jul-97	08-Aug-97	22-Sep-97		Rev #2
Amendment	20-Aug-97	22-Aug-97	05-Sep-97	22-Sep-97		Rev #2
Amendment	11-Sep-97	13-Sep-97	13-Sep-97	22-Sep-97		Rev #2
IR Letter					22-Sep-97	
BL	25-Sep-97	26-Sep-97	06-Oct-97	Current		

**NAME & ADDRESS OF APPLICANT:**

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13911 Ridgedale Drive, Suite 475  
Minnetonka, MN 55303

APPEARS THIS WAY  
ON ORIGINAL

**DRUG PRODUCT NAME:**

Proprietary: Sucraid  
Nonproprietary/USAN: sacrosidase  
Code Name/#: Code  
Chem.Type/Ther.Class: 1P V

**PHARMACOLOGICAL CATEGORY** Enzyme replacement therapy

**INDICATION:** Oral replacement therapy for CSID

**DOSAGE FORM:** Liquid      **STRENGTH:** 8,500 IU/mL

APPEARS THIS WAY  
ON ORIGINAL

**ROUTE OF ADMINISTRATION:** Oral

**HOW DISPENSED:**  Rx     OTC

APPEARS THIS WAY  
ON ORIGINAL

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOL.WT: See Chem Review #1

SUPPORTING DOCUMENTS: See Chem Rev #2

RELATED DOCUMENTS: N/A

CONSULTS: See Chem Review #1

APPROVED [unclear]  
ON [unclear]

REMARKS/COMMENTS: None

CONCLUSIONS & RECOMMENDATIONS: The applicant should be advised that Proposal 1 is acceptable with suggested modifications

/S/

10/9/97

Arthur B. Shaw, Ph. D.  
Chemist, HFD-180

APPROVED [unclear]  
ON [unclear]

/S/

10/9/97

Eric P. Duffy, Ph.D.  
Chemistry Team Leader, HFD-180

cc:

NDA 20-772

HFD-180/Division File/NDA 20-772

HFD-180/LTalarico

HFD-820/JGibbs

HFD-180/EDuffy

HFD-180/JChoudary

HFD-181/MMcNeil

R/D Init by: EDuffy 10/9/97

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ON [unclear]

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ON [unclear]

McNeil

SEP 16 1997

DIVISION OF GASTROINTESTINAL AND  
COAGULATION DRUG PRODUCTS

Review of Chemistry, Manufacturing, and Controls

NDA:# 20-772 CHEM REVIEW # 2 REVIEW DATE: September 16, 1997

DOCUMENT TYPE	DATES		ASSIGNED	REVIEW	LETTER	
	DOCUMENT	CDER				
ORIGINAL	06-May-97	07-May-97	30-May-97	09-Sep-97		Rev #1
Amendment	01-Jul-97	02-Jul-97	09-Jul-97	09-Sep-97		Rev #1
IR Letter					07-Jul-97	
Amendment	18-Jul-97	21-Jul-97	08-Aug-97	Current		
Amendment	20-Aug-97	22-Aug-97	05-Sep-97	Current		
Amendment	11-Sep-97	12-Sep-97	16-Sep-97	Current		

NAME & ADDRESS OF APPLICANT:

Orphan Medical, Inc.  
13911 Ridgedale Drive, Suite 475  
Minnetonka, MN 55303

APPEARS THIS WAY  
ON ORIGINAL

DRUG PRODUCT NAME:

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Nonproprietary/USAN: sacrosidase  
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Chem.Type/Ther.Class: 1P V

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APPEARS THIS WAY  
ON ORIGINAL

Redacted

2

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commercial

information



RELATED DOCUMENTS: N/A

CONSULTS: See Chem Review #1

REMARKS/COMMENTS: There are still problems with the batch record.

CONCLUSIONS & RECOMMENDATIONS: The applicant should be sent an Information Request (IR) letter.

2/16/97  
Arthur B. Shaw, Ph. D.  
Chemist, HFD-180

9/16/97  
Eric P. Duffy, Ph.D.  
Chemistry Team Leader, HFD-180

APPROVED BY  
ON 9/16/97

APPROVED BY  
ON 9/16/97

cc:

NDA 20-772

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HFD-181/MMcNeil

R/D Init by: EDuffy 9/16/97

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APPROVED BY  
ON 9/16/97

APPROVED BY  
ON 9/16/97

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ON 9/16/97

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DIVISION OF GASTROINTESTINAL AND  
COAGULATION DRUG PRODUCTS

Review of Chemistry, Manufacturing, and Controls

**NDA:# 20-772** CHEM REVIEW # 1 REVIEW DATE: June 12, 1997

<u>DOCUMENT TYPE</u>	<u>DATES</u>			<u>REVIEW</u>
	<u>DOCUMENT</u>	<u>CDER</u>	<u>ASSIGNED</u>	
ORIGINAL	06-May-97	07-May-97	30-May-97	Current
Amendment	01-Jul-97	02-Jul-97	09-Jul-97	Current

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APPROVED THIS DAY  
ON [unclear]

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**HOW DISPENSED:**  Rx     OTC

APPROVED THIS DAY  
ON [unclear]

APPROVED THIS DAY  
ON [unclear]

RELATED DOCUMENTS (if applicable):

ADDITIONAL INFORMATION  
ON FILE

CONSULTS: Microbiology

REMARKS/COMMENTS:

CONCLUSIONS & RECOMMENDATIONS: The application is approvable.  
The applicant should be sent an Information Request Letter.

**/S/**

4/8/97

Arthur B. Shaw, Ph. D.  
Chemist, HFD-180

**/S/**

9/8/97

Eric P. Duffy, Ph.D.  
Chemistry Team Leader, HFD-180

cc:

- NDA 20-772
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- HFD-180/LTalarico
- HFD-820/JGibbs
- HFD-180/EDuffy
- HFD-180/JChoudary
- HFD-92/RLipcv
- HFD-181/MMcNeil

R/D Init by: EDuffy 9/2/97

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ADDITIONAL INFORMATION  
ON FILE