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RESEARCH**

APPLICATION NUMBER:

21-196

CHEMISTRY REVIEW(S)

DIVISION OF NEUROPHARMACOLOGICAL DRUG PRODUCTS, HFD-120
REVIEW OF CHEMISTRY, MANUFACTURING, AND CONTROLS

NDA 21-196

CHEM. REVIEW #5

REVIEW DATE 03-JUN-02

SUBMISSION TYPE
AMENDMENT

DOCUMENT DATE
16-MAY-02

CDER DATE
17-MAY-02

ASSIGNED DATE
21-MAY-02

NAME AND ADDRESS OF APPLICANT

Orphan Medical, Inc.
13911 Ridgedale Drive, Suite 250
Minnetonka, MN 55305

DRUG PRODUCT NAME

Proprietary:
Nonproprietary/USAN [1966]:
Code Name/Number:
Chem. Type/Ther. Class:

Xyrem® oral solution
sodium oxybate

1P

PHARMACOLOGICAL CATEGORY/INDICATION

Reduce the incidence of cataplexy and to improve the
symptom of daytime sleepiness in patients with
narcolepsy

DOSAGE FORM

Oral Solution

STRENGTHS

500 mg/mL

ROUTE OF ADMINISTRATION

Oral

DISPENSED

XXX RX

--- OTC

SPECIAL PRODUCTS

--- Yes

XXX NO

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA

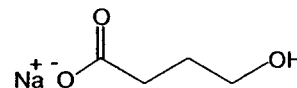
Sodium 4-hydroxybutyrate

4-Hydroxybutanoic acid monosodium salt

Sodium gamma hydroxybutyrate

C₄H₇NaO₃ Mol. Wt. 126.09

CAS Registry #: 502-85-2



sodium oxybate

SUPPORTING DOCUMENTS: IND --- IND --- (Treatment IND) and 12 packaging DMF's

RELATED DOCUMENTS: None

CONSULTS: None

REMARKS/COMMENTS: The sponsor has requested a 36-month expiry. The sponsor has submitted updated drug product stability from 6 drug product batches manufactured at --- and 4 drug product batches produced at ---. All batches were easily within specification. The impurity levels do not increase upon storage at 25°C; ---.

CONCLUSIONS & RECOMMENDATIONS: The requested tentative expiry of 36 months is acceptable.

cc: Orig. NDA 21-196
HFD-120
HFD-120/T Oliver
HFD-120/PM/AM Homonnay
HFD-120/MGuzewska
R/D Init by: MEG

Thomas F. Oliver, Ph.D., Chemist

Filename: n21196.05

2 page(s) have been removed because it contains trade secret and/or confidential information that is not disclosable.

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/s/

Thomas Oliver
6/3/02 01:44:43 PM
CHEMIST

Maryla Guzewska
6/3/02 01:49:00 PM
CHEMIST



CHEMISTRY REVIEW



NDA 21-196

Xyrem® (sodium oxybate) oral solution

Orphan Medical, Inc.

Chemistry Review

**Thomas F. Oliver, Ph.D.
HFD-120**

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