CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

020118Orig1s007

Trade Name: **SUPRANE**

Generic Name: Desflurane

Sponsor: Baxter Pharmaceutical Products, Inc.

Approval Date: 10/02/1999

Indications: SUPRANE (desflurane, USP) is indicated as an inhalation agent for induction and/or maintenance of anesthesia for inpatient and out patient surgery in adults

SUPRANE (desflurane, USP) is not recommended for induction of anesthesia in pediatric patients because of a high incidence of moderate to severe upper airway adverse events (see WARNINGS). After induction of anesthesia with agents other than SUPRANE, and tracheal intubation, SUPRANE is indicated for maintenance of anesthesia in infants and children.

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APPLICATION NUMBER:

020118Orig1s007

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APPLICATION NUMBER:

020118Orig1s007

APPROVAL LETTER

DEPARTMENT OF HEA H & HUMAN SERVICES

JF

Food and Drug Administration
Rockville MD 20857

NDA 20-118

Baxter Pharmaceutical Products Inc.
95 Spring Street
New Providence, NJ 07974

DEC 0 2 1999

Attention: Priya Jambhekar
Director, Regulatory Affairs

Dear Ms. Jambhekar:

Please refer to your supplemental new drug application dated July 27, 1999, received August 2, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Suprane® (desflurane, USP) Liquid for Inhalation.

The supplemental application provides for the use of alternative gasket(s) made of (b) (4) in place of (b) (4) as the product's closure valve.

We have completed the review of this supplemental application, and it is approved.

Please submit a sample of the valves used before and after the change.

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, call Laura Governale, Pharm.D., Regulatory Project Manager, at (301) 827-7410.

Sincerely,

Albinus D'Sa, Ph.D.
Chemistry Team Leader for the
Division of Anesthetic, Critical Care, and
Addiction Drug Products, HFD-170
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

cc:
Archival NDA 20-118
HFD-170/division file
HFD-170/L. Governale
HFD-170/M. Roberts
HFD-170/J. Ross
HFD-170/A. Goheer
HFD-170/A. D'Sa
HFD-170/C. Schumaker
HFD-170/C. McCormick
HFD-170/B. Rappaport
HFD-095/DDMS-IMT
HFD-yyy/DNDC Division Director
DISTRICT OFFICE

Drafted by: lg/December 1, 1999
Initialed by: cs/December 2, 1999
Final: ad/December 2, 1999
filename: 20118(Baxter)SNDA-I4.120199.doc

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APPLICATION NUMBER:

020118Orig1s007

CHEMISTRY REVIEW(S)

NOV 3 0 1999

Chemistry Review #1	1. Division 170	2. NDA Number 20-118
3. Name and Address of Applicant Baxter Pharmaceutical Products, Inc. 95 Spring Street New Providence, NJ 07974		4. Supplement Number Date SCP-007 7/27/99
5. Name of Drug Suprane (desflurane USP)	6. Nonproprietary Name Desflurane USP	
7. Supplement Provides for: alternative gasket(s) made of (b) (4) (b) (4) manufactured by (b) (4) for its closure valve.		8. Amendment(s) Sept. 28,1999
9. Pharmacological Category Anesthetic	10. How Dispensed Rx	11. Related Documents NDA 20-118/S-004 DMF (b) (4) Type III)
12. Dosage Form Liquid for Inhalation	13. Potency(ies) 100%	

14. Chemical Name and Structure see USAN

15. Comments

#1 The current closure for this system is a crimped on valve specifically designed to fit the filling port of the desflurane vaporizer (so as to avoid the possibility of filling the desflurane vaporizer with another inhalant). The crimped on valve includes a gasket and cap seal made of (b) (4) (b) (4) and a core seat gasket made of (b) (4) This closure system was approved as Supplement 004. Dec. 16,1997.

#2. The new proposed valve gaskets and cap seals will be made of (b) (4) Baxter maintains that this alternative gasket will provide some flexibility in the stocking of their packaging components and packaging operations. The valve design remains unchanged. See Attachment for illustration of design.

#3. The crimped-on valve will still be manufactured by (b) (4) and the product will still be manufactured and packaged at their approved site of: Baxter Caribe, Inc., Route 3, Km 142.5, Guayama Puerto Rico, 00784. (Note: Compliance has indicated that inspection of closure manufacturer is not necessary.)

#4. Information submitted to support this supplement: See Page 2

16. Conclusions and Recommendations
From a chemist viewpoint, the supportive information is acceptable and supplement should be approved.

17. Name	Signature	Date
Juanita Ross, M.S.	Juanita Ross	11/29/99
Team Leader Albinus D Sa, Ph.D.	ADSa	11/30/99

The applicant submitted following data to show that this change did not affect valve design or Product quality:

a) Three batches of Suprane (desflurane), HO35D7)1S, HO43D717S, and HO44D723S, packaged using the valves fitted with EPDM gaskets, core seats and cap seals were placed on stability at 25°C/60% RH for 24 months and at 40°C/75%RH(accelerated conditions) for 6 months each stored in both upright and sideways positions. The data recorded showed that the values for assay, impurity profile, non-volatile residue, and fluoride ion. appearance and pH were within the specification limits for Suprane (desflurane USP). (See pages 005-0014 of the submission)

b) Since desflurane is a volatile liquid (B.P. 22-23°C) a weight loss study was performed. Thirty two bottles of Suprane from each of the batches indicated above and ten empty bottles from each of the batches were weighed initially,, 3,6,9,18,and 24 months at 30°C
The weight loss data is relatively consistent from bottle to bottle at each time point.
The average weight loss over 24 months is approximately 0.3 g. **[my calculations show about 0.44 g, (.49 + .40 + .42 divided by 3)]** and the maximum weight loss for a single bottle is 0.6 g.

(b) (4)

[redacted]

cc:

NDA 20-118
HFD-170/Division File
HFD-170/RossJ
HFD-170/MilsteinJ, GovernaleL
Doc ID: NDA20118S7

1 Page(s) has been Withheld in Full as b4 (CCI/TS) immediately following this page

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

020118Orig1s007

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

RECORD OF TELEPHONE CONVERSATION/MEETING

DATE: 9-20-99

NDA NUMBER: 20-118

IND NUMBER:

TELECON/MEETING

INITIATED BY: ☐ APPLICANT/SPONSOR ☑ FDA

MADE: ☐ BY TELEPHONE ☐ IN PERSON

PRODUCT NAME: Suprane (Desflurane) USP Liquid for Inhalation

FIRM NAME: Baxter Pharm. Prods New Providence, NJ 07974

NAME AND TITLE OF PERSON WITH WHOM CONVERSATION WAS HELD: Priya Jambhekar Director Regulatory Affairs

TELEPHONE NO.: (908) 286-7215

In a telephone conversation with Ms Jambhekar, I asked the following questions:

1) Clarify difference in addresses

Cover letter dated 6/20/97
Ohmeda Pharmaceutical Prods. Div. Inc
P.O. Box 1110 Allen Road
Liberty Corner, New Jersey 07938-0804
and
Cover letter dated 7/27/99
Baxter Pharmaceutical Prods. Inc
95 Spring Street
New Providence, New Jersey

Response: Ms Jambhekar indicated she would reference the letter sent to the NDA explaining this transfer of ownership

2) Why ~~or~~ is the firm making a Change in these material of the Valve gaskets from [redacted] (b) (4)

SIGNATURE

DIVISION: HFD-170

FORM FD 2587 (11/77)

ORIGINAL IND/NDA

RECORD OF TELEPHONE CONVERSATION/MEETING

DATE

NDA NUMBER

IND NUMBER

TELECON/MEETING

INITIATED BY
☐ APPLICANT/SPONSOR
☐ FDA

MADE
☐ BY TELEPHONE
☐ IN PERSON

PRODUCT NAME

FIRM NAME

NAME AND TITLE OF PERSON WITH WHOM CONVERSATION WAS HELD

TELEPHONE NO.

3 Response: She will look this up and get back to me

3) Where is final product manufactured.

Response: She indicated

(b) (4)

She indicated that she will get back to me by Friday.

End of Conversation

Questions were satisfactorily answered in Amendment Sept. 28, 1999

SIGNATURE

DIVISION
HFD-170

FORM FD 2587 (11/77)

ORIGINAL IND/NDA