CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:NDA 20984

MICROBIOLOGY REVIEW(S)

REVIEW FOR HFD-170
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #2
6 April 1999

A. 1. NDA 20-984 BZ
APPLICANT: Organon, Inc.
375 Mt. Pleasant Avenue
West Orange, NJ 07052

2. PRODUCT NAME: Raplon® (rapacuronium bromide) for Injection

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
The product is an injectable preparation.

4. METHODS OF STERILIZATION:
The product is

5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:
The product is indicated as an adjunct to general anesthesia to facilitate tracheal intubation, and to provide skeletal muscle relaxation during surgical procedures.

B. 1. DATE OF INITIAL SUBMISSION: 24 June 1998

2. DATE OF AMENDMENT: 1 April 1999 (Subject of this Review)

3. RELATED DOCUMENTS: (none)

4. ASSIGNED FOR REVIEW: 4 April 1999

C. REMARKS: The submission is a response to deficiencies found in Microbiologist's Review #1 performed by Lynne Ensor, Ph.D.

D. CONCLUSIONS: The application is recommended for approval on the basis of sterility assurance.

/S/

7 Apr. / 1999

Paul Stinavage, Ph.D.

PAC 4/7/99

cc: Original NDA 20-984
HFD-170/A. D'sa/S. Samanta
HFD-805/Consult File/Stinavage

Drafted by: P. Stinavage, 6 April 1999
R/D initialed by P. Cooney

HFD 170/Ross

OCT 16 1998

REVIEW FOR HFD-170
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW NO. 1 OF NDA 20-984

October 9, 1998

A. 1. NDA: No. 20-984
SPONSOR: Organon Inc.
375 Mt. Pleasant Ave.
West Orange, NJ 07052

2. PRODUCT NAMES: RAPLON™ (Rapacuronium bromide)

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: A sterile lyophilized product of 100 mg strength in a 5 ml vial and 200 mg strength in a 100 ml vial. The product is to be reconstituted with sterile water for intravenous injection. Reconstituted solution must be used within 24 hours and may be stored at room temperature or refrigerated (2° - 25°C) till use. Single use only.

4. METHODS OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY: Non-depolarizing neuromuscular relaxant (used as an adjunct to general anesthesia during surgical procedures)

6. DRUG PRIORITY CLASSIFICATION: standard

B. 1. DATE OF INITIAL SUBMISSION: 25 June 1998

2. DATE OF AMENDMENT: none

3. RELATED DOCUMENTS: DMF , DMF DMF DMF DMF DMF

4. ASSIGNED FOR REVIEW: 31 August 1998

C. REMARKS:

D. CONCLUSIONS: This application is approvable contingent upon the outlined problem issues regarding sterility assurance being addressed. Specific comments are provided

/S/

Lynne A. Ensor, Ph.D.

PAC 10/16/98

cc:

Original NDA 20-984
HFD-160 Consult File
HFD-170/Ross/CSO
HFD-830/Ensor

drafted by: L. Ensor, 08/31/98

R/D initialed by: P. Cooney, 10/14/98