CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-351

MICROBIOLOGY REVIEW(S)

REVIEW TO HFD-580
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF/HFD-805
MICROBIOLOGY REVIEW #2 OF NDA

11 October 2001

A. 1. NDA: 21-351BI

2. TYPE OF SUPPLEMENT: N/A

3. SUPPLEMENT PROVIDES FOR: N/A

4. APPLICANT/SPONSOR: Watson Laboratories
417 Wakara Way
Salt Lake City, UT 84108

5. MANUFACTURING SITE:

6. DRUG PRODUCT NAME:
Proprietary: OXYTROL™
Nonproprietary: oxybutynin transdermal system
Drug Priority Classification: S

7. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY: Transdermal patch, — 3.9 mg/day

8. METHOD(S) OF STERILIZATION: N/A

9. PHARMACOLOGICAL CATEGORY: Anticholinergic

B. 1. DOCUMENT/LETTER DATE: April 26, 2001
2. RECEIPT DATE: April 26, 2001
3. CONSULT DATE: June 8, 2001
4. DATE OF AMENDMENT: August 3, 2001
5. ASSIGNED FOR REVIEW: September 12, 2001
6. SUPPORTING/RELATED DOCUMENTS: Microbiology review of NDA 21-351 (dated August 30, 2001)

C. REMARKS: This amendment contains the applicant's response to microbiology questions from the Agency. The applicant proposes to not have microbial limit release specifications for the drug product (a non-sterile transdermal).

D. CONCLUSIONS: This submission is recommended for approval on the basis of product quality microbiology.

Bryan S. Riley, Ph.D.
Microbiology Reviewer

cc.: Original NDA 21-351
HFD 580/Division File
HFD 580/Project Manager
HFD 580/Chemist
HFD 805/Consult File
HFD 805/ B. Riley

Drafted by: Bryan Riley, Ph.D.
R/D initialed by: Peter Cooney, Ph.D.

filename: C:\Data\Data\Word\NDA\21351BIr2.doc

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/s/

Bryan Riley
11/7/01 10:07:19 AM
MICROBIOLOGIST

Peter Cooney
11/7/01 10:50:27 AM
MICROBIOLOGIST

REVIEW TO HFD-580
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF/HFD-805
MICROBIOLOGY REVIEW #1 OF NDA

30 August 2001

A. 1. NDA: 21-351

2. TYPE OF SUPPLEMENT: N/A

3. SUPPLEMENT PROVIDES FOR: N/A

4. APPLICANT/SPONSOR: Watson Laboratories
417 Wakara Way
Salt Lake City, UT 84108

5. MANUFACTURING SITE:

6. DRUG PRODUCT NAME:
Proprietary: OXYTROL™
Nonproprietary: oxybutynin transdermal system
Drug Priority Classification: S

7. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY: Transdermal patch, [redacted] 3.9 mg/day

8. METHOD(S) OF STERILIZATION: N/A

9. PHARMACOLOGICAL CATEGORY: Anticholinergic

B. 1. DOCUMENT/LETTER DATE: April 26, 2001
2. RECEIPT DATE: April 26, 2001
3. CONSULT DATE: June 8, 2001
4. DATE OF AMENDMENT: N/A
5. ASSIGNED FOR REVIEW: August 8, 2001
6. SUPPORTING/RELATED DOCUMENTS:

C. REMARKS:

D. CONCLUSIONS: This submission is approvable, pending resolution of product quality microbiology deficiencies. Please see "Microbiologist's List of Deficiencies and Comments" at the end of this review.

Bryan S. Riley, Ph.D.
Microbiology Reviewer

cc.: Original NDA 21-351
HFD 580/Division File
HFD 580/Project Manager
HFD 580/Chemist
HFD 805/Consult File
HFD 805/ B. Riley

Drafted by: Bryan Riley, Ph.D.
R/D initialed by: Peter Cooney, Ph.D.

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/s/

Bryan Riley
8/30/01 10:54:54 AM
MICROBIOLOGIST

Peter Cooney
8/30/01 03:54:15 PM
MICROBIOLOGIST