CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-861s000

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

25 January 2008

NDA: 21-861/N-000-AZ

Drug Product Name
Proprietary: Patanase® Nasal Spray.
Non-proprietary: Olopatadine hydrochloride nasal spray.
Drug Product Priority Classification: S

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Review Request	Assigned to Reviewer
26 SEP 2007	27 SEP 2007	16 OCT 2007	17 JAN 2008*

*This assignment was originally made to Junia Beaubrun on 18 OCT 2007.

Applicant/Sponsor
Name: Alcon, Inc.
Address: PO Box 62
Bosch 69
CH-6331 Hunenberg,
Switzerland

Representative: Seane D. Jones
Address: 6201 South Freeway
Fort Worth, TX 76134-2099
Telephone: 817-568-6296

Name of Reviewer: John W. Metcalfe, Ph.D.

Conclusion: Recommend approval.

Product Quality Microbiology Data Sheet

A. 1. TYPE OF SUBMISSION: Resubmission of NDA.

2. SUBMISSION PROVIDES FOR: A formulation change to the subject drug product. The original NDA was submitted on 24 December 2004.

3. MANUFACTURING SITE:
Alcon Cusi S.A.
Camil Fabra, 58
08320 El Masnou (Barcelona), Spain

4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:

- Non-sterile, preserved solution (b) (4) 30 mL fill) in 30 mL plastic bottle.
- Multiple dose nasal spray.
- 0.6%.

5. METHOD(S) OF STERILIZATION: The product is not sterile.

6. PHARMACOLOGICAL CATEGORY: Indicated for the management and treatment of the symptoms of seasonal allergic rhinitis.

B. SUPPORTING/RELATED DOCUMENTS: Microbiology Review of NDA 21-861 (dated 20 JUN 2005).

C. REMARKS:
There is no ONDQA Initial Quality Assessment in DFS as of 18 JAN 2008.

The submission is provided in CTD format. This reviewer was given twelve white jacketed paper volumes (#s 1-12 of 20 volumes) for review.

The subject submission is an amendment to the original NDA submitted on 24 DEC 2004. A product quality microbiology review (dated 20 JUN 2005) was completed on the original submission, and recommended approval. The 20 JUN 2005 microbiology review pertained to microbial limits testing and preservative effectiveness testing. The subject amendment was submitted in response to the Agency's 27 OCT 2005 action letter which contained non microbiology related deficiencies. The resubmission includes a change in the formulation. As a result, this review will assess the revised formulation and its impact on both microbial limits and preservative effectiveness.

File Name: N021861N000AZR1.doc

Executive Summary

I. Recommendations

A. Recommendation on Approvability – NDA 21-861/N-000-AZ is recommended for approval on the basis of microbiological product quality.

B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable – N/A.

II. Summary of Microbiology Assessments

A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology -

(b) (4)

B. Brief Description of Microbiology Deficiencies - There are no microbiology deficiencies identified.

C. Assessment of Risk Due to Microbiology Deficiencies – Not applicable.

III. Administrative

A. Reviewer's Signature _____
John W. Metcalfe, Ph.D.

B. Endorsement Block_____
Bryan Riley, Ph.D.

C. CC Block
N/A

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/s/

John Metcalfe
1/28/2008 01:28:18 PM
MICROBIOLOGIST

Bryan Riley
1/28/2008 01:33:34 PM
MICROBIOLOGIST
I concur with the conlusions in this review.

Product Quality Microbiology Review
Review for HFD-000

20 JUNE 2005

NDA: 21-861

Drug Product Name
Proprietary: Patanase® Nasal Spray
Non-proprietary: olopatadine hydrochloride nasal spray 0.6%
Drug Product Priority Classification: 3S

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Consult Sent	Assigned to Reviewer
24 DEC 2004	27 DEC 2004	03 FEB 2005	01 MAR 2005

Applicant/Sponsor

Name:	Alcon Research, Ltd.
Address:	6201 South Freeway Fort Worth, TX 76234-2009
Representative:	Seane D. Jones Associate Director, Regulatory Affairs
Telephone:	(817) 568-6296
Name of Reviewer:	Janet Barletta, Ph.D.
Conclusion:	Recommended for approval based on microbiological product quality.

Product Quality Microbiology Data Sheet

A. 1. TYPE OF SUBMISSION: Original NDA submission

2. SUBMISSION PROVIDES FOR: Evaluation of:

- microbial limit test, and
- antimicrobial effectiveness test.

3. MANUFACTURING SITE: Alcon Cusi S.A.
Camil Fabra, 58
08320 El Mansou
(Barcelona), Spain

4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:

- 0.6%, or
- 600 mg w/v olopatadine as base.

5. METHOD(S) OF STERILIZATION: Non-sterile product.

6. PHARMACOLOGICAL CATEGORY: (b) (4) treatment of the symptoms of seasonal (b) (4) allergic rhinitis.

B. SUPPORTING/RELATED DOCUMENTS: N/A

C. REMARKS: N/A

filename: N021861r1.doc

Executive Summary

I. Recommendations

A. Recommendation on Approvability – Recommended for approval based on microbiological product quality.

B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable - N/A

II. Summary of Microbiology Assessments

A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology - Olopatadine Nasal 0.6% is a non-sterile product. Precautions are taken during the manufacturing process to insure microbiological control according to standard operating procedures. The microbial limit and the antimicrobial effectiveness test are applied.

B. Brief Description of Microbiology Deficiencies - N/A

C. Assessment of Risk Due to Microbiology Deficiencies - N/A

III. Administrative

A. Reviewer's Signature _____
(Janet Barletta, Ph.D.)

B. Endorsement Block
James L. McVey/Microbiology Team Leader
cc:
Original NDA 21-861
DFS

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/s/

Janet Barletta
6/20/05 10:13:33 AM
MICROBIOLOGIST

James McVey
6/20/05 12:40:14 PM
MICROBIOLOGIST