

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
22518Orig1s000

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

30 November 2009

NDA: 22-518/N-000

Drug Product Name

Proprietary:

Dulera.

Non-proprietary:

Mometasone furoate/formoterol fumarate.

Review Number: 1.

Dates of Submission(s) Covered by this Review

Letter	Stamp	Review Request	Assigned to Reviewer
21 MAY 2009	22 MAY 2009	16 SEP 2009	17 SEP 2009
13 NOV 2009	13 NOV 2009	N/A	N/A

Applicant/Sponsor

Name:

Schering Corporation

Address:

2000 Galloping Hill Rd.
Kenilworth, NJ 07033

Representative:

Susan Yule

Telephone:

908-740-7435

Name of Reviewer:

John W. Metcalfe, Ph.D.

Conclusion:

Recommend approval.

Product Quality Microbiology Data Sheet

- A. 1. **TYPE OF SUBMISSION:** Original NDA.
2. **SUBMISSION PROVIDES FOR:** A new drug product.
3. **MANUFACTURING SITE:**
3M health Care Ltd.
Derby Rd.
Loughborough
Leicestershire
LE11 5 SF
England
4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**
- Inhalation Aerosol.
 - Oral inhalation.
 - 200/5, 100/5, (b) (4) µg per actuation.
5. **METHOD(S) OF STERILIZATION:** The drug product is not sterile.
6. **PHARMACOLOGICAL CATEGORY:** The subject drug product is indicated for the treatment of asthma.
- B. **SUPPORTING/RELATED DOCUMENTS:** None.
- C. **REMARKS:**
The Request for Consultation comments/special instructions requests a review of topics pertaining to microbial limits.

The subject NDA is submitted electronically in the CTD format.

The following information request was provided to the OND PM on 02 October 2009 for dissemination to the applicant:

A microbiology review of NDA 22-518/N-000 is in progress. The New Drug Application references USP regarding the performance of microbial limits testing. Regardless, provide the following:

- The test methods which are used for performing microbial limits.
- Data demonstrating that the microbial limits test methods are suitable for use with the subject drug product. Reference is made to USP<61> which states in part, “The ability of the test to detect microorganisms in the presence of product to be tested must be established”.

The applicant amended the NDA with a response to this Information Request on 13 November 2009. The responses are summarized and reviewed in appropriate sections of this review.

File Name: N022518R1.doc

Executive Summary

I. Recommendations

- A. **Recommendation on Approvability** – NDA 22-518/N-000 is recommended for approval on the basis of product quality microbiology.
- B. **Recommendations on Phase 4 Commitments and/or Agreements, if Approvable** – Not applicable.

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** _____
Stephen Langille, Ph.D.
- C. **CC Block**
N/A

7 pages has been withheld in full as B(4) CCI/TS immediately following this page



Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22518	ORIG-1	SCHERING CORP	MOMETASONE FUROATE/FORMOTEROL FUMARATE

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JOHN W METCALFE
11/30/2009

STEPHEN E LANGILLE
12/01/2009

MEMORANDUM



DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: 19 October 2009

TO: Eunice H. Chung
Regulatory Project Manager
OND/ODEII/DPAP

FROM: John W. Metcalfe, Ph.D.
Review Microbiologist
CDER/OPS/New Drug Microbiology Staff
(301) 796-1576

SUBJECT: NDA 22-518/N-000 Mid-Cycle Update.
Submission Date: 22 May 2009
Drug Product: Dulera.
Applicant: Schering Plough.

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1. The following Information Request was forwarded to the OND Project Manager for dissemination to the applicant on 02 October 2009:

A microbiology review of NDA 22-518/N-000 is in progress. The New Drug Application references USP regarding the performance of microbial limits testing. Regardless, provide the following:

- The test methods which are used for performing microbial limits.
- Data demonstrating that the microbial limits test methods are suitable for use with the subject drug product. Reference is made to USP<61> which states in part, "The ability of the test to detect microorganisms in the presence of product to be tested must be established".

2. Microbiology reviewer's comment regarding mid-cycle review status.

Amending the NDA with the microbiology information requested above should not be a hardship for the applicant. Consequently, assuming that the applicant amends the NDA with the requested information, the issues raised in the Microbiology IR are not considered by this reviewer to be a major concern regarding the application's approvability. This reviewer expects to meet the requested review completion date of 15 Dec 2009.

END