

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22518Orig1s000

OTHER ACTION LETTER(s)



NDA 22-518

COMPLETE RESPONSE

Schering Corporation
2000 Galloping Hill Road
Kenilworth, NJ 07033-0530

Attention: Michael Belman
Director & Liaison, Global Regulatory Affairs

Dear Mr. Belman:

Please refer to your New Drug Application (NDA) dated May 21, 2009, received May 22, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Dulera (mometasone furoate/formoterol fumarate) Inhalation Aerosol (b) (4)

(b) (4)

We acknowledge receipt of your submissions dated June 4 and 16, July 1, 16 and 24, August 12 and 26, September 4 and 22, October 29, and November 4, 10, 13 and 25, 2009, and January 11, 14, 22 and 29, February 3, 12 and 16, March 5 and 16, May 21 and 26, and June 10, 11, 15, 18, 21, and 22, 2010.

We have completed our review of this application, as amended, and have determined that we cannot approve this application in its present form. We have described our reasons for this action below and, where possible, our recommendations to address these issues.

(b) (4)

LABELING

2. We reserve comment on the proposed labeling until the application is otherwise adequate. If you revise labeling, your response must include updated content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>.

SAFETY UPDATE

When you respond to the above deficiencies, include a safety update as described at 21 CFR 314.50(d)(5)(vi)(b). You are advised to contact the Division regarding the extent of your safety update prior to responding to this letter.

OTHER

Within one year after the date of this letter, you are required to resubmit or take one of the other actions available under 21 CFR 314.110. If you do not take one of these actions, we will consider your lack of response a request to withdraw the application under 21 CFR 314.65. A resubmission must fully address all the deficiencies listed. A partial response to this letter will not be processed as a resubmission and will not start a new review cycle.

Under 21 CFR 314.102(d), you may request a meeting or telephone conference with us to discuss what steps you need to take before the application may be approved. If you wish to have such a meeting, submit your meeting request as described in the FDA's "Guidance for Industry - Formal Meetings Between the FDA and Sponsors or Applicants", May 2009 at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM153222.pdf>.

The drug product may not be legally marketed until you have been notified in writing that this application is approved.

If you have any questions, call Eunice Chung, Regulatory Project Manager, at (301) 796-4006.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Director
Division of Pulmonary, Allergy, and
Rheumatology Products
Office of Drug Evaluation II
Office of New Drugs
Center for Drug Evaluation and Research

Application
Type/Number

Submission
Type/Number

Submitter Name

Product Name

NDA-22518

ORIG-2

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/

BADRUL A CHOWDHURY

06/22/2010