CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 090410

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 090410

Mylan Pharmaceuticals, Inc.
Attention: S. Wayne Talton
Vice President, Regulatory Affairs
781 Chestnut Ridge Road
P.O. Box 4310
Morgantown, WV 26504

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated March 13, 2008, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Budesonide Capsules, 3 mg (Enteric Coated).

Reference is also made to the tentative approval letter issued by this office on May 12, 2010, and to your amendments dated October 15, 2008; August 21, 2009; and March 3, 2011.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Budesonide Capsules, 3 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Entocort EC Capsules, 3 mg, of AstraZeneca LP. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA. The "interim" dissolution testing method and specifications are as follows:

Apparatus:	USP Apparatus 2 (paddle)
Medium:	Acid Stage: 0.1N HCl
	Buffer Stage: pH 6.8 Phosphate Buffer
Volume:	500 mL for both Acid Stage and Buffer Stage

The product should meet the following "interim" specifications:

Acid Stage: NMT (b) (4) of the labeled content is dissolved after 2 hours.

Buffer Stage:

Time (Hours)	Percent Dissolved
1	(b) (4)
2	
6	NLT (b) (4)

These "interim" dissolution test(s) and tolerances should be finalized by submitting dissolution data from the first three production size batches. These data should be submitted as a "Special Supplement – Changes Being Effected" if there are no revisions to be made to the "interim" specifications, or if the final specifications are tighter than the "interim" specifications. In all other instances, the information should be submitted as a Prior Approval Supplement.

The RLD upon which you have based your ANDA, Entocort EC Capsules of AstraZeneca LP (AstraZeneca), is subject to a period of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent No. 5,643,602 (the '602 patent) expires on January 1, 2015 (with pediatric exclusivity added).

Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '602 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Budesonide Capsules, 3 mg, under this ANDA. You have notified the agency that Mylan Pharmaceuticals, Inc. (Mylan) complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation was initiated against Mylan for infringement of the '602 patent within the statutory 45-day period in the United States District Court for the District of Delaware [AstraZeneca LP, Aktiebolaget Draco, KBI Inc. and KBI-E Inc. v. Mylan Pharmaceuticals, Inc., Civil Action No. 08-453]. Although this litigation remains ongoing, the 30-month period identified in section 505(j)(5)(B)(iii) of the Act, during which FDA was precluded from approving your ANDA, has expired.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

We note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the Act.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at

http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/U_CM072392.pdf The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
Center for Drug Evaluation and Research

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

/s/

KEITH O WEBBER
05/16/2011