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APPLICATION NUMBER:

ANDA 070920s020

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 70-920/S-019 S-020, S-023 and S-024

Mylan Pharmaceuticals Inc.
Attention: S. Wayne Talton
781 Chestnut Ridge Road
Morgantown, WV 26504-4310

Dear Sir:

This is in reference to your supplemental new drug application dated December 27, 2007, submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act, regarding your abbreviated new drug application for Temazepam Capsules USP, 15 mg and 30 mg.

Reference is also made to your amendments dated April 1, 2008, April 4, 2008, June 2, 2008 and October 8, 2008.

The supplemental applications, submitted as "Prior Approval Supplements", provide for the following changes:

S-019: Addition of dosage strength, Temazepam Capsules USP, 22.5 mg.

S-020: Labeling revision associated with the 22.5 mg strength.

S-023: Addition of dosage strength, Temazepam Capsules USP, 7.5 mg.

S-024: Labeling revision associated with the 7.5 mg strength.

We have completed the review of these supplemental applications, 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. However, because of the patent issue noted below, at this time we are unable to grant final approval to your Temazepam Capsules USP, 7.5 mg. Therefore, only your Temazepam Capsules USP, 22.5 mg is approved (S-019 and S-020). Your Temazepam Capsules USP, 7.5 mg, is **tentatively** approved(S-023 and S-024).

I. Approval of Temazepam Capsule USP, 22.5 mg

The Division of Bioequivalence has determined your Temazepam Capsules USP, 22.5 mg to be bioequivalent and, therefore, therapeutically equivalent to the listed drug, Restoril Capsules, 22.5 mg, of Mallinckrodt, Inc. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

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 505-1(i).

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(s) 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.

Within 14 days of the date of this letter, submit updated content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the approved labeling. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination. For

administrative purposes, please designate this submission as "***Miscellaneous Correspondence - SPL for Approved ANDA 70-920/ S-019 and S-020***".

II. Tentative Approval of Temazepam Capsules USP, 7.5 mg

We are unable at this time to grant final approval to your supplemental applications for Temazepam Capsules USP, 7.5 mg at this time because of the patent issue noted below. Therefore, the supplemental applications are **tentatively** approved. This determination is based upon information available to the agency at this time, (i.e., information in your ANDA and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacturing and testing of the drug product). This determination is subject to change on the basis of new information that may come to our attention.

The reference listed drug (RLD) upon which you have based your ANDA, Restoril Capsules, 7.5 mg**,** of Mallinckrodt Inc., 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. 5,211,954 (the '954 patent), is scheduled to expire on May 18, 2010. Your ANDA contains a paragraph III certification to the '954 patent under section 505(j)(2)(A)(vii)(III) of the Act stating that Mylan Pharmaceuticals will not market Temazepam Capsules USP, 7.5 mg prior to the expiration of the patent. Therefore, final approval of your supplemental applications may not be made effective pursuant to section 505(j)(5)(B)(ii) of the Act until the '954 patent has expired, currently, May 18, 2010.

To reactivate your supplemental applications prior to final approval, please submit a "MINOR AMENDMENT – FINAL APPROVAL REQUESTED" 90 days prior to the date you believe that your supplemental applications will be eligible for final approval. This amendment should provide the legal/regulatory basis for your request for final approval and should include a copy of a court decision, or a settlement or licensing agreement, as appropriate. It should also identify changes, if any, in the conditions under which the supplemental applications were tentatively approved, i.e., updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. This amendment should be submitted even if none of these changes were made, and it should be designated clearly in your cover letter as a MINOR AMENDMENT – FINAL APPROVAL REQUESTED.

In addition to the amendment requested above, the agency may request at any time prior to the date of final approval that you submit an additional amendment containing the requested information. Failure to submit either or, if requested, both amendments may result in rescission of the tentative approval status of your supplemental applications, or may result in a delay in the issuance of the final approval letter.

Any significant changes in the conditions outlined in this ANDA as well as changes in the status of the manufacturing and testing facilities' compliance with current good manufacturing practices (cGMPs) are subject to agency review before final approval of the application will be made. Such changes should be categorized as representing either "major" or "minor" changes, and they will be reviewed according to OGD policy in effect at the time of receipt. The submission of multiple amendments prior to final approval may also result in a delay in the issuance of the final approval letter.

This drug product may not be marketed without final agency approval under section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under section 301 of the Act. Also, until the agency issues the final approval letter, this drug product will not be deemed approved for marketing under section 505 of the Act, and will not be listed in the "Orange Book." Should you believe that there are grounds for issuing the final approval letter prior to May 18, 2010, you should amend your ANDA accordingly.

For further information on the status of this ANDA or upon submitting an amendment to the ANDA, please contact Benjamin Danso, Pharm.D, Project Manager, at 240-276-8527.

Sincerely yours,

{See appended electronic signature page}

Gary Buehler
Director
Office of Generic Drugs
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/

Robert L. West
6/12/2009 12:34:17 PM
Deputy Director, for Gary Buehler