DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 200043

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

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated July 24, 2009, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Armodafinil Tablets, 50 mg, 100 mg, 150 mg, 200 mg and 250 mg.[1]

Reference is made to the tentative approval letter issued by this office on January 19, 2012; and to your amendments dated April 4, May 10, and May 31, 2012.

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 insofar as it pertains to the 50 mg, 150 mg and 250 mg strengths, is approved, effective on the date of this letter. As explained below, the 100 mg and 200 mg strengths remain tentatively approved.

The RLD upon which you have based your ANDA, Cephalon's Nuvigil Tablets, is subject to periods of patent protection. The following patents and expiration dates (with pediatric exclusivity added) are currently listed in the Orange Book for this drug product:

[1] We note that the 100 mg and 200 mg strengths of the reference listed drug (RLD) upon which you have based your ANDA, Nuvigil Tablets of Cephalon Inc. (Cephalon), are no longer marketed in the U.S., and have been moved to the discontinued section of the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"). In the *Federal Register* of July 22, 2011 (76 FR 44012), the agency announced a determination that the 100 mg and 200 mg strengths of Nuvigil Tablets were not withdrawn from sale for reasons of safety or effectiveness. This determination allows the agency to continue to approve ANDAs for these discontinued strengths.

We also note that ANDA 200043 for Armodafinil Tablets, 50 mg, 150 mg and 250 mg, was received on July 24, 2009, and that a new strength amendment was received on October 5, 2009 (100 mg and 200 mg).

U.S. Patent Number	Expiration Date
7,132,570 (the '570 patent)	June 18, 2024
7,297,346 (the '346 patent)	May 29, 2024
RE37516 (the '516 patent)	April 6, 2015

With respect to each of these patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Armodafinil Tablets, 50 mg, 100 mg, 150 mg, 200 mg and 250 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 for infringement of the '516 and '570 patents was initiated against Mylan within the statutory 45-day period in the United States District Court for the District of Delaware [Cephalon, Inc. and Cephalon France v. Mylan Pharmaceuticals, Inc., Mylan Inc., Matrix Laboratories Limited, and Matrix Laboratories Inc., Civil Action No. 09-954]; and in the United States District Court for the Northern District of West Virginia [Cephalon, Inc. and Cephalon France v. Mylan Pharmaceuticals, Inc., Mylan Inc., Matrix Laboratories Limited, and Matrix Laboratories Inc., Civil Action No. 09-165]. Although this litigation remains ongoing, the 30-month period identified in section 505(j)(5)(B)(iii) of the Act, during which time FDA was precluded from approving your ANDA, has expired.

I. Approval of Armodafinil Tablets, 50 mg, 150 mg and 250 mg

The Division of Bioequivalence has determined your Armodafinil Tablets, 50 mg, 150 mg and 250 mg, to be bioequivalent and, therefore, therapeutically equivalent to the RLD, Cephalon's Nuvigil Tablets, 50 mg, 150 mg and 250 mg. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

With respect to 180-day generic drug exclusivity, Mylan was the first ANDA applicant to submit a substantially complete ANDA for Armodafinil Tablets, 50 mg, 150 mg and 250 mg, with paragraph IV certifications to one or more of the listed patents. Therefore, with this approval, Mylan is eligible for 180 days of generic drug exclusivity for Armodafinil Tablets, 50 mg, 150 mg, and 250 mg. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the agency of the date the exclusivity begins to run.

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.

Please 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(s) directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
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 Office of Prescription Drug Promotion 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.

II. Tentative Approval of Armodafinil Tablets, 100 mg and 200 mg

As noted above, your Armodafinil Tablets, 100 mg and 200 mg, remain tentatively approved. Prior to the submission of your ANDA, another applicant submitted a substantially complete ANDA for the 100 mg and 200 mg strengths and containing paragraph IV certifications to one or more of the listed patents. Your ANDA, insofar as it pertains to the 100 mg and 200 mg strengths, will be eligible for final approval on the date that is 180 days after the date the agency receives notice, with respect to the other ANDA, of the commercial marketing date identified in section 505(j)(5)(B)(iv) of the Act.

Our decision to tentatively approve your Armodafinil Tablets 100 mg and 200 mg, is based upon information currently available to the agency (i.e., data in your ANDA and the status of current good manufacturing practice (cGMP) of the facilities used in the manufacture and testing of the drug product). This decision is subject to change on the basis of new information that may come to our attention.

To reactivate this ANDA to provide for final approval of your Armodafinil Tablets, 100 mg and 200 mg, you must submit a "Supplemental Application – Expedited Review Requested." This supplemental application should be submitted for prior approval approximately 90 days prior to the date you believe that your Armodafinil Tablets, 100 mg and 200 mg, will be eligible for final approval. The supplement should include a detailed explanation of why and when you believe final approval should be granted. It should include updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. This supplement should be submitted even if no changes have been made to the application since the date of this tentative approval. Significant changes, as well as an update of the status of the manufacturing and testing facilities' compliance with cGMP are subject to agency review before final approval of the supplemental application will be granted. We request that you categorize the changes 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.

In addition to the supplemental application requested above, the agency may request at any time prior to the date of final approval that you submit an additional supplement containing the requested information. Failure to submit either or, if requested, both supplements may result in the rescission of the tentative approval status of your ANDA for your Armodafinil Tablets, 100 mg and 200 mg, or may result in a delay in the issuance of the final approval letter for this strength.

Please note that under section 505 of the Act, your Armodafinil Tablets, 100 mg and 200 mg, may not be marketed without final agency approval. The introduction or delivery for introduction

into interstate commerce of your 100 mg and 200 mg strengths before the final approval date is prohibited under section 301 of the Act. Also, until the agency issues the final approval letter, your Armodafinil Tablets, 100 mg and 200 mg, will not be deemed to be approved for marketing under section 505 of the Act, and will not be listed in the Orange Book.

For further information on the status of this ANDA, or prior to submitting additional amendments, please contact Sean Belouin, Project Manager, at (240) 276-8566.

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/

ROBERT L WEST

06/01/2012

Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.