DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 200156

Watson Laboratories, Inc.
Attention: Janie M. Gwinn
Director, Regulatory Affairs
311 Bonnie Circle
Corona, CA 92880

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated August 31, 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 March 8, 2012, and to your amendment dated April 6, 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 your Armodafinil Tablets 100 mg and 200 mg, is approved, effective on the date of this letter. As explained below, your Armodafinil Tablets 50 mg, 150 mg, and 250 mg remain tentatively approved.

[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(76 FR 44012), the agency announced a determination that the 100 mg and 200 mg strengths of Nuvigil Tablets were not withdrawn from sale for reasons of safety or effectiveness.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 200156 for Armodafinil Tablets, 150 mg and 250 mg, was received on September 1, 2009, and that new strength amendments were received on September 3, 2009 (200 mg) and September 8, 2009 (50 mg and 100 mg).

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:

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 Watson Laboratories, Inc. (Watson) complied with the requirements of section 505(j)(2)(B) of the Act, and litigation for infringement of the '570 patent was initiated against Watson within the statutory 45-day period in the United States District Court for the District of Delaware [Cephalon, Inc. and Cephalon France v. Watson Pharmaceuticals, Inc., Watson Laboratories, Inc. and Watson Pharma, Inc. (collectively "Watson"), Civil Action No. 1:2010-cv-00007-GMS]. 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, 100 mg and 200 mg

The Division of Bioequivalence has determined your Armodafinil Tablets, 100 mg and 200 mg, to be bioequivalent and, therefore, therapeutically equivalent to the RLD, Cephalon's Nuvigil Tablets, 100 mg and 200 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, Watson was the first ANDA applicant to submit a substantially complete ANDA for Armodafinil Tablets, 100 mg and 200 mg, with paragraph IV certifications to one or more of the listed patents. Amendments for these strengths were received by the agency on September 3, 2009 (200 mg) and September 8, 2009 (100 mg). As noted above, this ANDA was tentatively approved on March 8, 2012. This ANDA insofar as the 200 mg strength, therefore, was not granted tentative approval within the 30-month period described in section 505(j)(5)(D)(i)(IV). Nevertheless, the agency has

determined that the failure to obtain tentative approval within the 30-month period for the 200 mg strength was caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application was filed.[2] We therefore conclude that the 180-day exclusivity period described in section 505(j)(5)(B)(iv) of the Act was not forfeited by Watson, and that with this approval Watson is eligible for 180 days of generic drug exclusivity for Armodafinil Tablets, 100 mg and 200 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 commercial marketing begins.

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 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.

[2] There was both a change in and a review of the requirements for approval as a result of changes in the reference listed drug's labeling, including the addition of a REMS.

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, 50 mg, 150 mg and 250 mg

As noted above, your Armodafinil Tablets, 50 mg, 150 mg and 250 mg, remain tentatively approved. Prior to the submission of your ANDA, another applicant submitted a substantially complete ANDA for the 50 mg, 150 mg and 250 mg strengths and containing paragraph IV certifications to one or more of the listed patents. Your ANDA, insofar as it pertains to the 50 mg, 150 mg and 250 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 indentified in section 505(j)(5)(B)(iv) of the Act.

Our decision to tentatively approve your Armodafinil Tablets, 50 mg, 150 mg and 250 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 your ANDA for the 50 mg, 150 mg and 250 mg strengths prior to final approval, please submit a "Final Approval Request Amendment to Original #2" 90 days prior to the date you believe that this product will be eligible for final approval. Your amendment must provide a summary of the legal basis upon which you believe the ANDA should be approved, as well as:

1. updated information related to final-printed labeling or chemistry, manufacturing and controls data, a proposed REMS if a REMS is approved for the RLD at the time you reactivate your ANDA, or any other change in the conditions outlined in this ANDA, or

2. a statement that no such changes have been made to the ANDA since the date of tentative approval.

Any changes in the conditions outlined in this ANDA and the status of the manufacturing and testing facilities' compliance with current good manufacturing practice (cGMP) are subject to Agency review before final approval of your Armodafinil Tablets, 50 mg, 150 mg and 250 mg 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.

In addition to the amendment requested above, the agency may request at any time prior to the final date of approval that you submit an additional amendment containing the requested information. Failure to submit either amendment may result in rescission of this tentative approval determination, or delay in issuance of the final approval letter.

Your Armodafinil Tablets, 50 mg, 150 mg and 250 mg, may not be marketed without final agency approval under section 505 of the Act. The introduction or delivery for introduction into interstate commerce of a drug before the effective final approval date is prohibited under section 301 of the Act. Also, until the agency issues the final approval letter, the 50 mg, 150 mg and 250 mg strength products 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}

Gregory P. Geba, M.D., M.P.H.
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

08/29/2012

Deputy Director, Office of Generic Drugs,
for Gregory P. Geba, M.D., M.P.H.