



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22425/S-001

SUPPLEMENT APPROVAL

sanofi-aventis U.S., LLC
Attention: Marsha Miller, Ph.D.
Assistant Director, Regulatory Development
9 Great Valley Parkway
P.O. Box 3026
Malvern, PA 19355

Dear Dr. Miller:

Please refer to your Supplemental New Drug Application (sNDA) dated August 27, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Multaq (dronedaron hydrochloride) 400 mg Tablets.

We acknowledge receipt of your amendment dated September 23, 2010.

This "Prior Approval" supplemental new drug application provides for labeling revised as follows:

1. In the FULL PRESCRIBING INFORMATION: CONTENTS section, the following subsection titles have been added under ADVERSE REACTIONS:

6.1 Clinical Trials Experience
6.2 Postmarketing Experience
2. In the FULL PRESCRIBING INFORMATION: CONTENTS section, the title for section 14.3 has been revised to read:

ANDROMEDA Study (Increased Mortality in Patients with Severe or Recently Decompensated Heart Failure)
3. Under WARNINGS AND PRECAUTIONS, section 5.1 (Patients with New or Worsening Heart Failure during Treatment) has been changed from:

Advise patients to consult a physician if they develop signs or symptoms of heart failure, such as weight gain, dependent edema, or increasing shortness of breath. There are limited data available for AF/AFL patients who develop worsening heart failure during treatment with MULTAQ. If heart failure develops or worsens, consider the suspension or discontinuation of MULTAQ.

To:

Postmarketing cases of new onset and worsening heart failure have been reported during treatment with Multaq. Advise patients to consult a physician if they develop signs or symptoms of heart failure, such

as weight gain, dependent edema, or increasing shortness of breath. If heart failure develops or worsens, consider the suspension or discontinuation of MULTAQ.

4. Under ADVERSE REACTIONS, a new heading for Clinical Trials Experience has been added immediately following the bulleted items at the beginning of the section.
5. Under ADVERSE REACTIONS, the following has been added as a new Postmarketing Experience section:

6.2 Postmarketing Experience

The following adverse reaction has been identified during post-approval use of MULTAQ. Because these reactions are reported voluntarily from a population of an unknown size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Cardiac: Heart failure [*see Warnings and Precautions (5.1)*].

Postmarketing cases of new onset and worsening heart failure have been reported during treatment with MULTAQ.

6. Under CLINICAL STUDIES, the title of section 14.3 has been changed to:

ANDROMEDA Study (Increased Mortality in Patients with Severe or Recently Decompensated Heart Failure)

7. The revision and copyright dates have been updated.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

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(1)] in structured product labeling (SPL) format, as described at

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical to the enclosed labeling (text for the package insert, Medication Guide) and include the labeling changes proposed in any pending “Changes Being Effectuated” (CBE) supplements and any annual reportable changes not included in the enclosed labeling. 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/UCM072392.pdf>.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(1)(1)(i)] in MS Word format that includes the changes approved in this supplemental application.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at <http://www.fda.gov/opacom/morechoices/fdaforms/cder.html>; instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Russell Fortney, Regulatory Project Manager, at (301) 796-1068.
Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, Pharm.D.
Deputy Director for Safety
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure: Content of Labeling

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

/s/

MARY R SOUTHWORTH
02/11/2011