DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022425/S-027

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT

Sanofi-aventis U.S., LLC
Attention: Cristina Di Ramio, Pharm.D.
Manager, North America & Global Regulatory Affairs
55 Corporate Drive
Mail Stop 55C-205A
Bridgewater, NJ 08807

Dear Dr. Di Ramio:

Please refer to your Supplemental New Drug Application (sNDA) dated and received January 20, 2016, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Multaq (dronedarone) 400 mg Tablets.

We also refer to our REMS Modification Notification letter dated December 22, 2015, and we acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated November 18, 2015.

We further reference our Approval letter for Supplement 27 (S-027) dated February 12, 2016. The letter dated February 12, 2016 incorrectly referenced Multaq (dronedarone) 200 mg Tablets, rather than the correct dose of 400 mg Tablets. This letter supersedes the letter dated February 12, 2016. The action date will remain the same, February 12, 2016.

This prior approval supplemental new drug application provides for proposed modification to the approved REMS and proposes to eliminate the requirement for the approved REMS for Multaq (dronedarone).

APPROVAL

We have completed our review of this supplemental application, and it is approved, effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Multaq was originally approved on July 1, 2009, and the most recent modification was approved on March 19, 2014. The REMS consists of a communication plan, and a timetable for submission of assessments of the REMS.

Your proposed modifications consist of elimination of the communication plan and, therefore, release from the requirement for a REMS for Multaq (dronaderone).

As communicated in the December 22, 2015 REMS Modification Notification Letter, we determined a communication plan is no longer necessary to include as an element of the approved REMS because the

communication plan has been completed and the most recent assessment demonstrates that the communication plan has met its goals.

Therefore, because the communication plan is no longer necessary to ensure the benefits of the drug outweigh the risks, a REMS is no longer required for Multaq (dronedarone).

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:

Lori Anne Wachter, RN, BSN, RAC
Regulatory Project Manager for Safety
(301) 796-3975

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, PharmD.
Deputy Director for Safety
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
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/

MARY R SOUTHWORTH
02/12/2016