NDA 22-425 Multaq® (dronedarone)

sanofi-aventis U.S. 55 Corporate Boulevard
Bridgewater, New Jersey 08807

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOALS

- To prevent Multaq® use in patients with:
  - Symptomatic heart failure with recent decompensation requiring hospitalization or NYHA Class IV heart failure
  - Permanent atrial fibrillation (AF) that will not or cannot be cardioverted into normal sinus rhythm
- To inform healthcare professionals about the serious risks of Multaq®, including:
  - Increased risk of cardiovascular death in patients with symptomatic heart failure with recent decompensation requiring hospitalization or NYHA Class IV heart failure
  - Increased risk of cardiovascular death, heart failure and stroke in patients with permanent AF
  - Signs and symptoms of liver injury and hepatic failure

II. REMS ELEMENTS

A. COMMUNICATION PLAN

Sanofi-aventis will implement a Communication Plan to inform healthcare professionals (HCPs) of the risks associated with the use of Multaq®, safe and appropriate prescribing information, and the goals of the REMS.

The Communication Plan includes:

1. *Healthcare Professional Information Sheet*
   a. The *Healthcare Professional Information Sheet* is intended to highlight the important safety information for Multaq. The Information Sheet provides a high-level reminder for HCPs for each point of the prescribing process: initiation of therapy, patient counseling and ongoing management and follow-up. This sheet thereby re-enforces the goals of the

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REMS and actions to ensure appropriate use. The Healthcare Professional Information Sheet will be posted on the REMS website within 15 days and continue for a period of 5 years after drug approval.

The *Healthcare Professional Information Sheet* is a part of the REMS and is appended.

2. *Dear Healthcare Provider Letters*

   a. *Important drug warning about increased risk of death, stroke and heart failure in patients with permanent atrial fibrillation treated with Multaq®*. This Dear Healthcare Provider letter provided an update to an important drug warning about the increased risk of cardiovascular events and death in patients with permanent AF treated with Multaq®. Additionally, the need to discontinue Multaq® in patients who develop or progress toward permanent AF while on Multaq® was highlighted. This DHCP letter was posted on the REMS website (www.multaqrems.com) within 15 days after the approval of the permanent AF REMS modification (June 2012) and will continue for a period of 1 year from approval of that REMS modification (June 2013).

   The Dear Healthcare Provider letter (permanent AF) is part of the REMS and is appended.

   b. *Important drug warning about hepatic failure in patients treated with Multaq®*. This Dear Healthcare Provider letter provided an important drug warning about hepatic failure in patients treated with Multaq® and the signs and symptoms that both HCPs and patients should monitor. This DHCP letter was posted on the REMS website (www.multaqrems.com) within 15 days after the approval of the hepatic REMS modification (August 2011) and will continue for 1 year after the corresponding REMS modification approval (August 2012).

   The Dear Healthcare Provider letter (hepatic) is part of the REMS and is appended.

3. *Healthcare Provider Checklist*

   a. Sanofi-aventis will post the updated prescriber checklist, which provides key evaluation points for the HCP at the point of prescribing, to the REMS website within 15 days of this REMS modification approval. The Checklist will assist the HCP in the identification of contraindications for use as well as highlight the warnings and precautions for use when considering treatment with Multaq®. The Healthcare Provider Checklist will also be made available via sales and/or medical representatives and through the Sponsor's Medical Information Services Department.

   The updated Healthcare Provider Checklist is part of the REMS and is appended.

4. *REMS Print Advertising in Professional Society Journals*

   a. Sanofi-aventis issued REMS Print Advertisements for approximately 30 months in each of the following professional society journals since product approval:

      i. Journal of the American College of Cardiology

      ii. Circulation

      iii. Annals of Internal Medicine

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REMS Print Advertisements have been discontinued as the 24 month commitment was met.

5. *The REMS website*

   a. Sanofi-aventis will ensure the REMS webpage, www.multaqrems.com, includes a link to the updated REMS materials as well as the two following FDA Drug Safety Communications: Severe liver injury associated with the use of dronedarone (marketed as Multaq) [1/14/2011] and Review update of Multaq (dronedarone) and increased risk of death and serious cardiovascular adverse events [12/19/2011]. The REMS webpage will be available for 5 years after drug approval.

   The modified REMS website is part of the REMS and is appended.

B. TIMETABLE FOR SUBMISSION OF ASSESSMENTS

Sanofi-aventis will submit REMS Assessments to the FDA annually for years 1-5 and at year 7. Assessment reports are due on the 31st of December. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for the assessment. Sanofi-aventis will submit each assessment so that it will be received by the FDA on or before the due date.

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1. MULTAQ® HEALTHCARE PROFESSIONAL INFORMATION SHEET

RISK MITIGATION PROGRAM
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for Appropriate Care and Treatment

Health Care Professional Information Sheet for MULTAQ® (dronedarone)

MULTAQ is an antiarrhythmic drug indicated to reduce the risk of hospitalization for AFib in patients in sinus rhythm with a history of paroxysmal or persistent AFib. Multaq is available in 400-mg tablets.

FDA has required a Risk Evaluation and Mitigation Strategy (REMS) to ensure the benefits of MULTAQ outweigh the risks.

Boxed Warning

WARNING:
INCREASED RISK OF DEATH, STROKE AND HEART FAILURE IN PATIENTS WITH DECOMPENSATED HEART FAILURE OR PERMANENT ATRIAL FIBRILLATION

MULTAQ is contraindicated in patients with symptomatic heart failure with recent decompensation requiring hospitalization or NYHA Class IV heart failure. MULTAQ doubles the risk of death in these patients.

MULTAQ is contraindicated in patients in atrial fibrillation (AFib) who will not or cannot be cardioverted into normal sinus rhythm. In patients with permanent AFib, MULTAQ doubles the risk of death, stroke, and hospitalization for heart failure.

MULTAQ doubles the risk of death and is therefore contraindicated in the following populations:

- **Permanent atrial fibrillation:** Patients treated with MULTAQ should undergo monitoring of cardiac rhythm no less often than every 3 months. Cardiovert patients who are in AFib (if clinically indicated) or discontinue MULTAQ. MULTAQ offers no benefit in subjects in permanent AFib. In this population, MULTAQ was associated with an increased risk of stroke, particularly in the first two weeks of therapy. MULTAQ should only be initiated in patients in sinus rhythm who are receiving appropriate antithrombotic therapy
- **Symptomatic heart failure with recent decompensation requiring hospitalization or NYHA Class IV heart failure**

For a complete list of contraindications, please refer to the prescribing information, including boxed WARNING.

In the postmarketing setting, the following REMS-related risks have been reported:

- **New onset or worsening heart failure:** In a placebo-controlled study in patients with permanent AFib, increased rates of heart failure were observed in patients with normal left ventricular function and no history of symptomatic heart failure, as well as those with a history of heart failure or left ventricular dysfunction. If heart failure develops or worsens and requires hospitalization, discontinue MULTAQ
- **Hepatocellular liver injury, including acute liver failure requiring transplant:** Consider obtaining periodic hepatic serum enzymes, especially during the first 6 months of treatment, but it is not known whether routine periodic monitoring of serum enzymes will prevent the development of severe liver injury. If hepatic injury is suspected, promptly discontinue MULTAQ and test serum enzymes, aspartate aminotransferase (AST), alanine aminotransferase (ALT), and alkaline phosphatase, as well as serum bilirubin, to establish whether there is liver injury. If liver injury is found, institute appropriate treatment and investigate the probable cause. Do not restart MULTAQ in patients without another explanation for the observed liver injury

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Please consider the following *Steps for Ensuring Appropriate Use* when prescribing MULTAQ for your patients:

1. Appropriate Patient Selection

- Screen patients for severity and stability of heart failure; MULTAQ is contraindicated in patients with NYHA Class IV heart failure or symptomatic heart failure with recent decompensation requiring hospitalization because it doubles the risk of death
- MULTAQ is contraindicated in patients with permanent AFib that will not or cannot be cardioverted into normal sinus rhythm
- MULTAQ should only be initiated in patients in sinus rhythm who are receiving appropriate antithrombotic therapy. In a placebo-controlled study in patients with permanent AFib, MULTAQ was associated with an increased risk of stroke, particularly in the first two weeks of therapy
- STOP treatment with Class I or III antiarrhythmics (e.g., amiodarone, flecainide, propafenone, quinidine, disopyramide, dofetilide, sotalol) or drugs that are strong inhibitors of CYP 3A (e.g., ketoconazole) before starting MULTAQ
- The dosage of certain cardiovascular medications may need to be adjusted and certain laboratory test changes may occur. These cardiovascular medications include statins, calcium-channel blockers, sirolimus, tacrolimus, beta-blockers, and other CYP 2D6 substrates, digoxin, dabigatran, and warfarin

2. Patient Monitoring

- Observe patients for new onset or worsening of heart failure. If heart failure develops or worsens and requires hospitalization, discontinue MULTAQ® (dronedarone)
- Patients treated with dronedarone should undergo monitoring of cardiac rhythm no less often than every 3 months. Cardiovert patients who are in AFib (if clinically indicated) or discontinue MULTAQ. MULTAQ offers no benefit in patients in permanent AFib
- Monitor patients for signs and symptoms of liver injury. Consider obtaining periodic hepatic serum enzymes, especially during the first 6 months of treatment, but it is not known whether routine periodic monitoring of serum enzymes will prevent the development of severe liver injury
- Patients should be carefully evaluated clinically for pulmonary toxicity. If confirmed, treatment should be discontinued
- Renal function should be monitored periodically in patients treated with MULTAQ as increases in creatinine and renal failure have been reported in the postmarketing setting. In most cases, these effects appear to be reversible after discontinuation of MULTAQ

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3. Patient Counseling

- 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
- Advise patients to immediately report symptoms suggesting hepatic injury (such as anorexia, nausea, vomiting, fever, malaise, fatigue, right upper quadrant pain, jaundice, dark urine, or itching) to their physician
- Advise patients that MULTAQ should not be taken with certain other medications and to consult with their physicians before starting any new drugs, as the dosage of certain cardiovascular medication may need to be adjusted
- Refer patients to the Medication Guide and address any additional questions

Please refer to the enclosed Prescribing Information for complete safety information before prescribing MULTAQ.

Serious Adverse Events

Health care professionals should report any serious adverse events thought to be associated with MULTAQ use to sanofi-aventis at 1-800-633-1610, option 2, or visit www.multaqrems.com.

Alternatively, report this information to FDA's MedWatch reporting system by phone (1-800-FDA-1088), facsimile (1-800-FDA-0178), online (https://www.accessdata.FDA.gov/scripts/medwatch/), or mail using the MedWatch for FDA 3500, to the FDA Medical Products Reporting Program, 5600 Fishers Lane, Rockville, MD 20852-9787.

Additional Resources

For additional information, talk to your sanofi-aventis sales representative, call sanofi-aventis Medical Information Services department at 1-800-633-1610, option 1, or visit www.multaqrems.com. Additionally, refer patients to the MULTAQ Medication Guide.

For full prescribing information, including boxed WARNING, please see enclosed PI or refer to the link on www.multaqrems.com, the site from which this page was downloaded.

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2. DEAR HEALTHCARE PROFESSIONAL LETTERS

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A. PERMANENT AFIB DHCPL

December 2011

IMPORTANT DRUG WARNING

SANOFI

Increased Risk of Death, Stroke and Heart Failure in Patients with Permanent Atrial Fibrillation treated with Multaq (Dronedarone)

Dear Healthcare Provider:

In August 2011, Sanofi communicated preliminary information on the premature termination of the PALLAS (Permanent Atrial fibriLLAtion outcome Study using Dronedarone on top of standard therapy) study due to increased risk of CV death, stroke, and heart failure events.

Following adjudication and final analysis of the PALLAS data and subsequent update and FDA-approval of the United States Prescribing Information (USPI), Sanofi would like to provide you with highlights of the important updates to the Multaq USPI pertaining to PALLAS and permanent atrial fibrillation (AF).

In addition to an update to the heart failure contraindication, the boxed warning for Multaq has been expanded to include permanent AF (AF patients who will not or cannot be cardioverted into normal sinus rhythm). The boxed warning now reads as follows:

WARNING:
INCREASED RISK OF DEATH, STROKE AND HEART FAILURE IN PATIENTS WITH DECOMPENSATED HEART FAILURE OR PERMANENT ATRIAL FIBRILLATION

MULTAQ is contraindicated in patients with symptomatic heart failure with recent decompensation requiring hospitalization or NYHA Class IV heart failure. MULTAQ doubles the risk of death in these patients.

MULTAQ is contraindicated in patients in atrial fibrillation (AF) who will not or cannot be cardioverted into normal sinus rhythm. In patients with permanent AF, MULTAQ doubles the risk of death, stroke, and hospitalization for heart failure.

The following has also been added to the **WARNINGS AND PRECAUTIONS** section of the Multaq USPI:

5 WARNING AND PRECAUTIONS

5.2 Cardiovascular Death and Heart Failure in Permanent AF
MULTAQ doubles the risk of cardiovascular death (largely arrhythmic) and heart failure events in patients with permanent AF. Patients treated with dronedarone

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should undergo monitoring of cardiac rhythm no less often than every 3 months. Cardiovert patients who are in atrial fibrillation (if clinically indicated) or discontinue MULTAQ. MULTAQ offers no benefit in subjects in permanent AF.

5.3 Increased Risk of Stroke in Permanent AF
In a placebo-controlled study in patients with permanent atrial fibrillation, dronedarone was associated with an increased risk of stroke, particularly in the first two weeks of therapy. MULTAQ should only be initiated in patients in sinus rhythm who are receiving appropriate antithrombotic therapy.

Additionally, the indication for Multaq has been updated to help ensure its appropriate use in paroxysmal or persistent atrial fibrillation (i.e. non-permanent AF patients). **Multaq is indicated to reduce the risk of hospitalization for atrial fibrillation in patients in sinus rhythm with a history of paroxysmal or persistent atrial fibrillation (AF).**

In accordance with these changes, the Multaq Medication Guide has been updated to include this information. **We encourage you to discuss the new important safety information outlined in this letter and the updated Multaq USPI and Medication Guide with your patients** (the link to the current Prescribing Information, including Medication Guide, has been provided below for your review).

Also of note, Sanofi is collaborating with the FDA to appropriately update the Multaq Risk Evaluation and Mitigation Strategy (REMS). You will be notified of the changes to the Multaq REMS program once it is FDA-approved.

Please note the information above does not contain all changes to the Multaq USPI. Please refer to the full Prescribing Information for Multaq for complete details.

For additional information, please contact Sanofi Medical Information Services at 1-800-633-1610 (option 1). Healthcare professionals should report adverse events suspected to be associated with the use of Multaq to Sanofi at 1-800-633-1610 (option 2).

Alternatively, report this information to FDA's MedWatch reporting system by phone (1-800-FDA- 1088), by facsimile (1-800-FDA-0178), online (https://www.accessdata.fda.gov/scripts/medwatch/) or mailed, using the MedWatch for FDA 3500, to the FDA Medical Products Reporting Program,
5600 Fishers Lane, Rockville, MD 20852-9787.

Sincerely,

Paul H. Chew, M.D.

Paul H. Chew, MD
US Chief Science Officer/Chief Medical Officer
sanofi-aventis U.S.

Click here for full Prescribing Information, including Boxed Warning.
This letter was prepared with the guidance of FDA.

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B. HEPATIC DHCPL

Initial Release: January 14, 2011
Revised to reflect updated Prescribing Information and REMS: June 2011

IMPORTANT DRUG WARNING

sanofi aventis
Because health matters

Hepatic Failure in Patients Treated with Multaq (Dronedarone)

Dear Healthcare Provider:

The purpose of this letter is to inform you of new important safety information for Multaq®, an antiarrhythmic. Multaq® was approved in July 2009 with an FDA required Risk Evaluation and Mitigation Strategy (REMS). The REMS has been modified to include informing healthcare professionals and patients about the serious risks of liver injury and hepatic failure with Multaq®.

Several cases of hepatocellular liver injury and hepatic failure have occurred in patients receiving Multaq (dronedarone), including two post-marketing reports of acute hepatic failure requiring transplantation. Multaq is indicated to reduce the risk of cardiovascular hospitalization in patients with paroxysmal or persistent atrial fibrillation (AF) or atrial flutter (AFL), with a recent history of AF/AFL and associated cardiovascular risk factors (age >70, hypertension, diabetes, prior cerebrovascular accident, left atrial diameter ≥ 50 mm or left ventricular ejection fraction <40%) who are in sinus rhythm or who will be cardioverted.

Healthcare professionals should advise patients treated with Multaq to immediately report symptoms suggesting hepatic injury (such as anorexia, nausea, vomiting, fever, malaise, fatigue, right upper quadrant pain, jaundice, dark urine, or itching) and should consider obtaining periodic hepatic serum enzymes, especially during the first 6 months of treatment. It is not known whether routine periodic monitoring of serum enzymes will prevent the development of severe liver injury. If hepatic injury is suspected, Multaq should be promptly discontinued and testing of serum enzymes, aspartate aminotransferase (AST), alanine aminotransferase (ALT) and alkaline phosphatase, as well as the serum bilirubin, should be performed to establish whether there is liver injury. If liver injury is found, appropriate treatment should be instituted and investigations should be performed to establish the probable cause. Multaq should not be restarted in patients without another explanation for the observed liver injury.

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The two cases of acute hepatic failure requiring transplantation occurred at 4.5 and 6 months after initiation of Multaq in patients with previously normal hepatic serum enzymes. Both patients were female and approximately 70 years of age.

In the first case, the patient had underlying intermittent atrial fibrillation, arterial hypertension and stable coronary artery disease. She was treated with Multaq for 4.5 months. Two weeks prior to hospitalization she reported increased exhaustion and tiredness. One week prior to admission she discontinued Multaq, and at the time of admission she was noted to have jaundice, coagulopathy, transaminitis and hyperbilirubinemia, which progressed to hepatic encephalopathy over the next nine days. A pre-transplant workup did not reveal another etiology of liver failure.

In the second case, the patient had a medical history of paroxysmal atrial fibrillation and Sjögren's syndrome. Following 6 months of treatment with Multaq she developed weakness, abdominal pain, coagulopathy, transaminitis and hyperbilirubinemia. She was transplanted 1 month later; no alternative etiology for liver failure was identified in the transplant work-up. In both cases, the explanted liver showed evidence of extensive hepatocellular necrosis.

The Prescribing Information for Multaq has been revised to include this information (the link to the current Prescribing Information has been provided below for your information). **We encourage you to discuss the new important safety information outlined in this letter with your patients.**

Healthcare professionals should report cases of hepatic injury and failure or any serious adverse events suspected to be associated with the use of Multaq to sanofi-aventis at 1-800-633-1610 (option 2).

Alternatively, report this information to FDA's MedWatch reporting system by phone (1-800-FDA-1088), by facsimile (1-800-FDA-0178), online (https://www.accessdata.fda.gov/scripts/medwatch/) or mailed, using the MedWatch for FDA 3500, to the FDA Medical Products Reporting Program, 5600 Fishers Lane, Rockville, MD 20852-9787.

Sincerely,

Paul H. Chew, MD
US Chief Science Officer/Chief Medical Officer
sanofi-aventis U.S.

Click here for full Prescribing Information, including Boxed Warning.
This letter was prepared with the guidance of FDA.

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3. HEALTHCARE PROVIDER CHECKLIST

MULTAQ® (Dronedarone) Health Care Professional Checklist

RISK MITIGATION PROGRAM
MPACT™
MULTAQ® Partnership for Appropriate Care and Treatment

This checklist is intended to assist health care professionals with identifying the appropriate patients for MULTAQ.

MULTAQ is indicated to reduce the risk of hospitalization for atrial fibrillation (AFib) in patients in sinus rhythm with a history of paroxysmal or persistent AFib. MULTAQ is available in 400-mg tablets.

The following are contraindications for use with MULTAQ.
Permanent AFib that will not or cannot be cardioverted into normal sinus rhythm
Symptomatic heart failure with recent decompensation requiring hospitalization or NYHA Class IV heart failure
2nd or 3rd degree AV block, or sick sinus syndrome (except when used in conjunction with a functioning pacemaker)
Bradycardia <50 bpm
Concomitant use of strong CYP 3A inhibitors, such as ketoconazole, itraconazole, voriconazole, cyclosporine, telithromycin, clarithromycin, nefazodone, and ritonavir
Concomitant use of drugs or herbal products that prolong the QT interval and might increase the risk of Torsade de Pointes, such as phenothiazine antipsychotics, tricyclic antidepressants, certain oral macrolide antibiotics, and Class I and III antiarrhythmics
Liver or lung toxicity related to the previous use of amiodarone
A QTc Bazett interval ≥500 ms or PR interval >280 ms
Severe hepatic impairment
Pregnancy (Category X): patients who are or may become pregnant
Nursing mothers
Hypersensitivity to the active substance or to any of the excipients

The following information was derived from WARNINGS and PRECAUTIONS	
• Cardiac rhythm should be monitored (≤q3 months)	• Potassium should be within normal range prior to and maintained in the normal range during administration of MULTAQ
• MULTAQ should only be initiated in patients in sinus rhythm who are receiving appropriate antithrombotic therapy	• Onset of dyspnea or non-productive cough may be related to pulmonary toxicity and patients should be carefully evaluated clinically
• Advise patients to consult a physician if they develop signs or symptoms of heart failure	• Monitor renal function periodically
• Consider obtaining periodic hepatic serum enzymes, especially during the first 6 months of treatment	

For full Prescribing Information, including boxed WARNING, please see enclosed PI or refer to the link on multaqrems.com, the site from which this page was downloaded.

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4. THE REMS WEBSITE

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RISK MITIGATION PROGRAM
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for Appropriate Care and Treatment

For U.S. Healthcare Professionals Only

SEARCH TEXT SIZE

Important Safety Information | Prescribing Information, Including Boxed WARNING | Medication Guide | Print

MULTAQ (dronedarone): REMS Information for Health Care Professionals

The Food and Drug Administration has required a Risk Evaluation and Mitigation Strategy (REMS) for MULTAQ. A REMS is a strategy to manage known or potential serious risk(s) associated with a drug product, and is required by the Food and Drug Administration to ensure that the benefits of the drug outweigh its risks.

The MULTAQ REMS program, also referred to as uPACT, is designed to inform health care professionals, including cardiologists, electrophysiologists, hospitalists, internal medicine, family practice physicians, and hospital, clinical, and retail pharmacists about the risks with MULTAQ. Additionally, nurse practitioners and physician assistants who work in offices of the above-mentioned physicians will also be targeted.

To learn more about the serious risks of MULTAQ, CLICK HERE for full Prescribing Information, including boxed WARNING.

The goals of the MULTAQ REMS are:

- To prevent MULTAQ use in patients with:
  - —Symptomatic heart failure with recent decompensation requiring hospitalization or NYHA Class IV heart failure
  - —Permanent atrial fibrillation (AF) who will not or cannot be cardioverted into normal sinus rhythm
- To inform healthcare professionals about the serious risks of MULTAQ, including:
  - —Increased risk of cardiovascular death in patients with symptomatic heart failure with recent decompensation requiring hospitalization or NYHA Class IV heart failure
  - —Increased risk of cardiovascular death, heart failure and stroke in patients with permanent AF
  - —Signs and symptoms of liver injury and hepatic failure

Materials for Healthcare Providers:

DOWNLOAD THE HCP INFORMATION SHEET

DOWNLOAD THE HCP CHECKLIST

DOWNLOAD DEAR HCP LETTER - HEPATIC

To read the FDA Drug Safety Communication: Severe liver injury associated with the use of dronedarone (marketed as MULTAQ), please CLICK HERE.

DOWNLOAD DEAR HCP LETTER - PERMANENT AFIB

To read the FDA Drug Safety Communication: Review update of MULTAQ (dronedarone) and increased risk of death and severe cardiovascular adverse events, please CLICK HERE.

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/s/

MARY R SOUTHWORTH
03/19/2014