NDA 21-085, NDA 21-277 Avelox® (moxifloxacin hydrochloride)
Tablets and I.V. Solution
Class of Product: Fluoroquinolone
Bayer Healthcare Pharmaceuticals Inc.

P.O. Box 1000
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RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL:

The goal of the REMS is to inform patients of the serious risk associated with the use of Avelox®, particularly the increased risk of tendinitis and tendon rupture.

II. REMS ELEMENTS:

A. Medication Guide

A Medication Guide (MG) will be dispensed with each Avelox® prescription.

Pursuant to 21 CFR 208.24, the MG will be made available in sufficient numbers to US Avelox® distributors. US distributors will provide the MG with every pharmacy shelf carton of Avelox® to ensure its availability for dispensing to patients who are dispensed Avelox®. The label of each container or package of Avelox® will include a prominent instruction to authorized dispensers to provide a MG to each patient to whom the drug is dispensed, and state how the MG is provided.

B. Communication Plan

The REMS for Avelox® does not include a Communication Plan.

C. Elements to Assure Safe Use

The REMS for Avelox® does not include Elements to Assure Safe Use.

D. Implementation System

Because this REMS for Avelox® does not include Elements to Assure Safe Use, an implementation system is not required.

III. Assessment of REMS

Results that have become available from the individual assessment activities as well as corrective actions and other pertinent information will be summarized in REMS Assessment Reports that will be submitted to FDA at 18 months, 3 years, and 7 years after the REMS is approved.