

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
022560Orig1s000

REMS

NDA 22-560
Atelvia™ (risedronate sodium) Delayed-Release Tablets

Bisphosphonate Drug Class

Warner Chilcott (US), LLC
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RISK EVALUATION AND MITIGATION STRATEGY (REMS):

I. GOAL

The goal of the REMS is to inform patients about the serious risks associated with the use of Atelvia including the possible risk of unusual thigh bone fractures.

II. REMS ELEMENTS

A. Medication Guide

Warner Chilcott (US), LLC will ensure that a Medication Guide will be dispensed with each Atelvia prescription and in accordance with 21 CFR 208.24.

B. Timetable for Submission of Assessments

Warner Chilcott (US), LLC will submit REMS Assessments to the FDA 18 months, 3 years and 7 years from the date of the approval of the REMS. 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 that assessment. Warner Chilcott (US), LLC will submit each assessment so that it will be received by FDA on or before the due date.

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/s/

AUDREY L GASSMAN
01/25/2011