FDA-REQUIRED REMS* SAFETY INFORMATION

Boxed Warning: Severe Diarrhea and Cardiac Toxicities with FARYDAK Treatment

Dear <<insert contact name here>>:

The FDA has required Novartis to distribute this safety notice as part of the FARYDAK® REMS (Risk Evaluation and Mitigation Strategy) program. We request that you inform your members about the following serious risks of FARYDAK.

Severe Diarrhea
• Severe diarrhea occurred in 25% of FARYDAK-treated patients

Cardiac Toxicities
• Severe and fatal cardiac ischemic events, severe arrhythmias, and ECG changes have occurred with FARYDAK

Please see the enclosed REMS Factsheet, a non-promotional factsheet reviewed by the FDA, for more detailed safety information. The factsheet and other important information are also available at www.FARYDAK-REMS.com.

Indication
FARYDAK, a histone deacetylase inhibitor, in combination with bortezomib and dexamethasone, is indicated for the treatment of patients with multiple myeloma who have received at least 2 prior regimens, including bortezomib and an immunomodulatory agent.

This indication is approved under accelerated approval based on progression-free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

*A REMS (Risk Evaluation and Mitigation Strategy) is a program required by the FDA to manage known or potential serious risks associated with a drug product. Please visit www.FARYDAK-REMS.com for more information.

Sincerely,

Novartis Pharmaceuticals Corporation
FDA REQUIRED REMS® SAFETY INFORMATION

Boxed Warning: Severe Diarrhea and Cardiac Toxicities with FARYDAK®

Dear [please insert recipient name here],

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Severe Diarrhea

- Severe diarrhea occurred in 25% of FARYDAK-treated patients

Cardiac Toxicities

- Severe and fatal cardiac ischemic events, severe arrhythmias, and ECG changes have occurred with FARYDAK.

Please see the ILMM at www.farydak.com, a non-promotional prescribing information reviewed by the FDA, for more detailed safety information. The fact sheet and other important information are also available at www.FARYDAK-REMS.com

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A REMS (Risk Evaluation and Mitigation Strategy) is a program required by the FDA to manage known or potential benefits and risks associated with a drug product. Please visit www.FARYDAK-REMS.com for more information.

Sincerely,

Novartis Pharmaceuticals Corporation

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