



June 25, 2010

**Immediate Attention Required  
Urgent Drug Recall:**

**COUMADIN® Tablets (Warfarin Sodium Tablets, USP) Crystalline, 1 mg,  
Sample, Blisters of 10  
Isopropanol Below Specification**

<b>Strength</b>	<b>Lot Number</b>	<b>Item Number</b>	<b>Expiration</b>
<b>1 mg</b>	<b>9A48931A</b>	<b>016910</b>	<b>31-JAN-2012</b>
<b>1 mg</b>	<b>9A48931B</b>	<b>016910</b>	<b>31-JAN-2012</b>
<b>1 mg</b>	<b>9A48931C</b>	<b>016910</b>	<b>31-JAN-2012</b>
Dates of distribution: July 2009 through April 2010			

Dear Health Care Practitioner:

Bristol-Myers Squibb Company is initiating a voluntary recall of blister pack samples of the COUMADIN 1 mg Tablet lots listed above. Our records indicate that you may have received samples from the subject lots through a Bristol-Myers Squibb sales representative or through a Bristol-Myers Squibb direct mail sample program. The recall is based upon Bristol-Myers Squibb’s determination that some tablets, over time, may not meet specification for isopropanol, which is required to maintain the active ingredient in a crystalline state.

This recall is being conducted as a precautionary measure to the sample dispensing level with the knowledge of the US Food and Drug Administration (FDA), and is limited to the specific lots, dosage and packaging listed above.

Our medical assessment of this situation indicates that there does not appear to be a clinically important risk related to COUMADIN 1 mg Tablets in regard to isopropanol level. However, use of tablets with low isopropanol could, in some cases, potentially lead to patient-to-patient variation in bioavailability. All other product characteristics, including warfarin sodium assay, are within specification.

**It is important that you carefully follow these recall instructions:** Please check your sample inventory for COUMADIN 1 mg Tablet samples from the subject lots. If you have inventory from these specified lots, please cease dispensing and return these samples along with the completed Business Reply Card to Bristol-Myers Squibb’s recall vendor, Stericycle, using the enclosed prepaid shipping label. Please complete and return the enclosed Business Reply Card even if you do not have any of the recalled stock in your possession. Be certain to carefully review your lot numbers and return only the subject lots of COUMADIN 1 mg Tablet samples listed above.



## Bristol-Myers Squibb Company

Please note that sales representatives are not permitted to handle sample product once it has been disbursed to a health care practitioner. Therefore they should not be engaged in this aspect of the recall process. We appreciate your cooperation with this request.

If you have any questions about this recall, please refer to the contact numbers below for assistance:

Recall Logistics	Stericycle 1-877-546-0128
General Inquiries	Bristol-Myers Squibb Customer Relations 1-800-332-2056 (option 1, then option 4)
Medical Inquiries	Bristol-Myers Squibb Medical Information 1-800-321-1335 (option 5)

We regret any inconvenience this matter may have caused. We sincerely appreciate your cooperation and thank you for your assistance.