



February 6, 2006

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John M. Gray  
President and CEO  
Healthcare Distribution Management Association  
901 North Glebe Road  
Suite 1000  
Arlington, Virginia 22203

Dear Mr. Gray:

I would like to thank you for your letter of December 20, 2005 expressing the problems distributors are experiencing with the isotretinoin new risk management program, iPLEDGE, that is to become fully implemented on March 1, 2006.

In a December 29, 2005 meeting between your organization and FDA it was agreed that we would not delay the launch date of December 30, 2005 but delay the date upon which wholesalers will be required to report data on product shipment and transactions to Covance, March 1, 2006.

We acknowledge the issues you are experiencing with the new program and ask that you notify the Agency of any additional difficulties being experienced by wholesalers when using the activated pharmacies database.

We look forward to continuing to work with your organization.

Sincerely,

A handwritten signature in cursive script, appearing to read "Steven Galson".

Steven Galson, M.D., MPH  
Director  
Center for Drug Evaluation and Research