



iPLEDGE™
Committed to Pregnancy Prevention

iPLEDGE—Committed to Pregnancy Prevention
One Radnor Corporate Center, Suite D300
Radnor, PA 19087

Dear Wholesaler or Chain Drug Executive,

The isotretinoin manufacturers are pleased to announce that the United States Food and Drug Administration (FDA) has approved iPLEDGE, an enhanced pregnancy risk management program designed to minimize fetal exposure to isotretinoin. This special restricted distribution program strives to ensure that:

- No female patient starts isotretinoin therapy if pregnant
- No female patient on isotretinoin therapy becomes pregnant

The iPLEDGE program requires registration of all wholesalers distributing isotretinoin, all healthcare professionals prescribing isotretinoin, all pharmacies dispensing isotretinoin, and **all male and female** patients prescribed isotretinoin; the program covers all isotretinoin products (brand and generic products).

For the purpose of the iPLEDGE program, the term wholesaler refers to a wholesaler and each of its individual distribution centers, a distributor and each of its individual distribution centers, and/or each warehousing chain pharmacy distribution center.

Key Elements of the iPLEDGE Program, Which Relate to Your Business Practices, Are:

- Beginning November 1, 2005, manufacturers of isotretinoin will only provide isotretinoin to wholesalers that are registered in the program.
- To be registered, each wholesaler must agree to meet all iPLEDGE requirements for wholesale distribution of isotretinoin products by completing the enclosed agreement.
- Wholesalers will be notified of incomplete agreements in order to complete their registrations.
- Beginning November 1, 2005, wholesalers will **ONLY** ship isotretinoin to
 - wholesalers registered in the iPLEDGE program with prior written consent from the manufacturer, or
 - pharmacies registered with and activated in the iPLEDGE program.
- The registration of wholesalers that do not abide by the terms of the agreement will be revoked after an investigation process, and manufacturers of FDA-approved isotretinoin products will not continue to provide them with isotretinoin for distribution.

To Register in the iPLEDGE Program, Mail the Completed Agreement to:

iPLEDGE—Committed to Pregnancy Prevention
One Radnor Corporate Center, Suite D300
Radnor, PA 19087

OR

Fax the completed form, using the following iPLEDGE fax number: 1-866-495-0660

Registration in the iPLEDGE program expires in 12 months and requires reregistration annually.

Once registered, you will receive instructions to report, on or after November 1, 2005, any request for isotretinoin from a pharmacy not registered and activated in the iPLEDGE program or from an unregistered wholesaler. These instructions will provide an e-mail address and a template to use for notification of pharmacy or wholesaler non-compliance. iPLEDGE will follow up with the pharmacy or wholesaler regarding completion of wholesaler registration or pharmacy registration and activation.

Please be advised that wholesaler registration is a critical aspect of the program and that your prompt attention is necessary to minimize any disruption in the supply of isotretinoin to you.

Thank you for supporting the success of the iPLEDGE program.

