



iPLEDGE™

Committed to Pregnancy Prevention

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

On Behalf of the Wholesaler Listed Below, I Acknowledge That:

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. To distribute isotretinoin, wholesalers must be registered with iPLEDGE and agree to meet all iPLEDGE requirements for wholesale distribution of isotretinoin products. Wholesalers must register with iPLEDGE by signing and returning this agreement that affirms they will comply with all iPLEDGE requirements for distribution of isotretinoin. 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. Each distribution center operated by a wholesaler must register if they are to distribute isotretinoin. These requirements include:

- Registering prior to distributing isotretinoin and reregistering annually thereafter
- Distributing only FDA-approved isotretinoin product obtained directly from the isotretinoin manufacturers (or delegate) or another registered wholesaler
- Beginning November 1, 2005 only ship isotretinoin to
 - wholesalers registered in the iPLEDGE program with prior written consent from the manufacturer, or
 - pharmacies licensed in the US and registered and activated in the iPLEDGE program
- Notifying immediately the isotretinoin manufacturer (or delegate) of any non-registered and/or non-activated pharmacy or unregistered wholesaler that attempts to order isotretinoin
- Complying with inspection of wholesaler records by the isotretinoin manufacturer (or delegate) for verification of compliance with the iPLEDGE program
- Returning to the manufacturer (or delegate) any undistributed product if registration is revoked by the iPLEDGE program or if the wholesaler chooses to not reregister annually
- Providing, at no charge, product flow data to manufacturer (or delegate); a subset of the EDI 867 Product Transfer and Resale and/or 852 Product Activity Data transaction sets or similar inventory tracking system data will be required. These data will be used strictly for product tracking and program compliance purposes. Data may be shared with the isotretinoin manufacturers (or other delegates), the Food and Drug Administration, other appropriate regulatory bodies to the extent violations of laws they enforce are identified, and parties violating the iPLEDGE program to the extent necessary to correct their violations.

An agreement must be completed for each distribution center.

I am authorized to execute this agreement on behalf of the Wholesaler (and its distribution centers, if applicable).

Wholesaler's Name _____
(Type or Print)

Distribution Center's DEA# _____

Distribution Center's Address _____

Distribution Center's City _____

Distribution Center's State _____ Distribution Center's ZIP _____

Distribution Center's Phone Number _____

Distribution Center's Fax Number _____

Authorized Representative _____
(print-first, MI, last)

Title _____

E-mail Address for Key Contact _____

E-mail Address for Pharmacy Eligibility File Delivery* _____

Authorized Representative's Signature _____

Date ____/____/____
M D Y

This agreement expires 12 months from agreement date. Annual registration is required.

* The list of registered and activated pharmacies will be e-mailed to this address daily.