

Food and Drug Administration
Dockets Management
5630 Fishers Lane, Room 1061
ROCKVILLE

0120 6 JUL 11 09:34

2006D-0226

I oppose the petition.

The Prescription Drug Marketing Act of 1987 (PDMA), as modified by the Prescription Drug Amendments of 1992, amended sections 301, 303, 503, and 801 of the Federal Food, Drug, and Cosmetic Act (the Act) to establish requirements related to the wholesale distribution of prescription drugs.

A primary purpose of the PDMA was to increase safeguards to prevent the introduction and retail sale of substandard, ineffective, and counterfeit drugs in the U.S. drug supply chain.

FDA has a legal obligation to protect the public, however delayed this to the point it will never be enforced.

"Based on concerns raised by various stakeholders, the agency delayed the effective date of §§ 203.3(u) and 203.50 several times."

"In February 2004, FDA delayed the effective date of §§ 203.3(u) and 203.50 until December 1, 2006, in part because we were informed by stakeholders in the U.S. drug supply chain that the industry would **voluntarily implement** electronic track and trace technology by 2007."

.."it appears that the use of electronic pedigree will not be widely adopted by 2007." (See **insert FR cite when published.**)

FDA cites "**Factors to Consider for Enforcement Focus**", however enforcement was absent. In absent of enforcement, the public is bound. FDA instead relied on voluntary implementation, and nothing happened.

2006D-0226

C1

Are there prior cases of the drug being counterfeited or diverted in the U.S.? Is there a history of false pedigrees associated with the product?

Phentermine to misbrand is attached. Iplex is misbranded attached.

*David Lowe
Ida, MI*



Comparison Shopping for Products [Mortgages](#) [Travel](#) [Schools](#) [More](#)

NexTag Search

All Categories

[Most Popular](#) | [Top Brands](#) | [Recently Viewed](#)

Showing 1 - 15 of 16 matches as a list | [show as grid](#)



PHENTERMINE 37.5 mg 90 tablets

Phentermine is the #1 weight loss diet pill in the U.S.A. Phentermine helps you lose weight!

Rating: ★★★★★ (5 user ratings) [\[rate this item\]](#)

[See All Prescription Drugs](#) | [See More Like This](#)

Stacker Sale

\$69.00

Buy at Seller



PHENTERMINE 37.5mg 30 pills

Phentermine is the #1 weight loss diet pill in the U.S.A. Phentermine helps you lose weight!

Rating: ★★★★★ (2 user ratings) [\[rate this item\]](#)

[See All Prescription Drugs](#) | [See More Like This](#)

Stacker Sale

\$49.95

Buy at Seller



PHENTERMINE 37.5 60 Tablets

Phentermine is the #1 weight loss diet pill in the U.S.A. Phentermine helps you lose weight!

Rating: ★★★★★ (1 user rating) [\[rate this item\]](#)

[See All Prescription Drugs](#) | [See More Like This](#)

Stacker Sale

\$69.00

Buy at Seller



PHENTERMINE Yellow 30mg (30 caps)

This medication is used in combination with a diet plan to help you reduce weight.

Rating: *No user ratings* [\[rate this item\]](#)

[See All Prescription Drugs](#) | [See More Like This](#)

Stacker Sale

\$79.95

Buy at Seller



PHENTERMINE blue 30 mg 30 Capsules

Phentermine is used as an appetite suppressant in conjunction with an overall diet plan to reduce weight.

Rating: *No user ratings* [\[rate this item\]](#)

[See All Prescription Drugs](#) | [See More Like This](#)

DrugsHome.com

\$84.13

Buy at Seller



PHENTERMINE blue 30 mg 60 Capsules

Phentermine is used as an appetite suppressant in conjunction with an overall diet plan to reduce weight.

Rating: *No user ratings* [\[rate this item\]](#)

[See All Prescription Drugs](#) | [See More Like This](#)

DrugsHome.com

\$117

Buy at Seller



PHENTERMINE 37.5 mg 30 Capsules

Phentermine is used as an appetite suppressant in conjunction with an overall diet plan to reduce weight.

Rating: *No user ratings* [\[rate this item\]](#)

[See All Prescription Drugs](#) | [See More Like This](#)

DrugsHome.com

\$70.76

Buy at Seller



PHENTERMINE blue 30 mg 90 Capsules

Phentermine is used as an appetite suppressant in conjunction with an overall diet plan to reduce weight.

Rating: *No user ratings* [rate this item]
 See All Prescription Drugs | See More Like This
 DrugsHome.com

\$141
 Buy at Seller



PHENTERMINE yellow 30 mg 30 Capsules

Phentermine is used as an appetite suppressant in conjunction with an overall diet plan to reduce weight.

Rating: *No user ratings* [rate this item]
 See All Prescription Drugs | See More Like This
 DrugsHome.com

\$83.80
 Buy at Seller



PHENTERMINE yellow 30 mg 60 Capsules

Phentermine is used as an appetite suppressant in conjunction with an overall diet plan to reduce weight.

Rating: *No user ratings* [rate this item]
 See All Prescription Drugs | See More Like This
 DrugsHome.com

\$106
 Buy at Seller



PHENTERMINE 37.5 mg 90 Capsules

Phentermine is used as an appetite suppressant in conjunction with an overall diet plan to reduce weight.

Rating: *No user ratings* [rate this item]
 See All Prescription Drugs | See More Like This
 DrugsHome.com

\$122
 Buy at Seller



PHENTERMINE yellow 30 mg 90 Capsules

Phentermine is used as an appetite suppressant in conjunction with an overall diet plan to reduce weight.

Rating: *No user ratings* [rate this item]
 See All Prescription Drugs | See More Like This
 DrugsHome.com

\$128
 Buy at Seller



PHENTERMINE 15 mg 90 Capsules

Phentermine is used as an appetite suppressant in conjunction with an overall diet plan to reduce weight.

Rating: *No user ratings* [rate this item]
 See All Prescription Drugs | See More Like This
 DrugsHome.com

\$185
 Buy at Seller



PHENTERMINE 15 mg 30 Capsules

Phentermine is used as an appetite suppressant in conjunction with an overall diet plan to reduce weight.

Rating: *No user ratings* [rate this item]
 See All Prescription Drugs | See More Like This
 DrugsHome.com

\$90.18
 Buy at Seller

PHENTERMINE 37.5 mg 60 Capsules

Phentermine is used as an appetite suppressant in conjunction with an overall diet plan to reduce weight.

Rating: *No user ratings* [rate this item]

\$107
 Buy at Seller



PHENTERMINE blue 30 mg 90 Capsules

Phentermine is used as an appetite suppressant in conjunction with an overall diet plan to reduce weight.

Rating: *No user ratings* [rate this item]
 See All Prescription Drugs | See More Like This
 DrugsHome.com

\$141
 Buy at Seller



PHENTERMINE yellow 30 mg 30 Capsules

Phentermine is used as an appetite suppressant in conjunction with an overall diet plan to reduce weight.

Rating: *No user ratings* [rate this item]
 See All Prescription Drugs | See More Like This
 DrugsHome.com

\$83.80
 Buy at Seller



PHENTERMINE yellow 30 mg 60 Capsules

Phentermine is used as an appetite suppressant in conjunction with an overall diet plan to reduce weight.

Rating: *No user ratings* [rate this item]
 See All Prescription Drugs | See More Like This
 DrugsHome.com

\$106
 Buy at Seller



PHENTERMINE 37.5 mg 90 Capsules

Phentermine is used as an appetite suppressant in conjunction with an overall diet plan to reduce weight.

Rating: *No user ratings* [rate this item]
 See All Prescription Drugs | See More Like This
 DrugsHome.com

\$122
 Buy at Seller



PHENTERMINE yellow 30 mg 90 Capsules

Phentermine is used as an appetite suppressant in conjunction with an overall diet plan to reduce weight.

Rating: *No user ratings* [rate this item]
 See All Prescription Drugs | See More Like This
 DrugsHome.com

\$128
 Buy at Seller



PHENTERMINE 15 mg 90 Capsules

Phentermine is used as an appetite suppressant in conjunction with an overall diet plan to reduce weight.

Rating: *No user ratings* [rate this item]
 See All Prescription Drugs | See More Like This
 DrugsHome.com

\$185
 Buy at Seller



PHENTERMINE 15 mg 30 Capsules

Phentermine is used as an appetite suppressant in conjunction with an overall diet plan to reduce weight.

Rating: *No user ratings* [rate this item]
 See All Prescription Drugs | See More Like This
 DrugsHome.com

\$90.18
 Buy at Seller

PHENTERMINE 37.5 mg 60 Capsules

Phentermine is used as an appetite suppressant in conjunction with an overall diet plan to reduce weight.

Rating: *No user ratings* [rate this item]

\$107
 Buy at Seller

Introducing
 **IPLEX**
 mecasermin rinfabate
 (rDNA origin) injection

IPLEX (mecasermin rinfabate [rDNA origin] injection) is indicated for the treatment of growth failure in children with severe primary IGF-I deficiency (Primary IGFD) or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH.

Therapy with IPLEX should be directed by physicians experienced in the diagnosis and treatment of patients with growth disorders. It is contraindicated in patients with closed epiphyses, active or suspected neoplasia, or an allergy to IPLEX. Because of insulin-like hypoglycemic effects, IPLEX should be administered at approximately the same time each day, and patients should avoid missing meals and a balanced diet. Tonsillar and adenoid hypertrophy was reported in a clinical trial; patients should have periodic examinations to detect potential complications of adenotonsillar enlargement. Headache was reported in 8/36 children in a clinical trial. Papilledema was reported in a clinical trial, including one case with increased intracranial pressure that resolved with revision of a blocked existing ventriculoperitoneal shunt. Please refer to the full Prescribing Information.

Learn More:

- ▶ [Prescribing Information](#)
- ▶ [Patient Instructions for IPLEX™](#) → 
- ▶ [Statement of Medical Necessity](#) → 
- ▶ [In the News](#)
- ▶ [About Insmed](#)

INSMED INCORPORATED To learn more, please call 1-866-GO-IPLEX (1-866-464-7539) or visit us online at www.insmed.com
 Copyright 2006, Insmed Inc., All Rights Reserved. | [Privacy Statement](#)