

US FDA Cracks Down on Importation of Unapproved New Drugs for Personal Use, According to Newly Updated Import Alert #66-41

Investigating and detaining shipments of imported personal-use drugs has historically been deemed an unjustified expenditure of FDA resources because most personal-use drug imports are small in amount and value. However, the U.S. FDA is recently demonstrating increased enforcement regarding the importation of unapproved new drugs for personal use; as demonstrated by FDA's Import Alert #66-41. Benjamin England, founder of [FDAImports.com, LLC](http://FDAImports.com) states that "This Import Alert has been expanded to include importers and products of drugs imported strictly for personal use rather than just targeting foreign shippers, which is FDA's normal M.O."

The United States Food and Drug Administration ("FDA") is cracking down on the importation of unapproved new drugs with regards to personal use. Import Alert #66-41, "Detention Without Physical Examination of Unapproved New Drugs Promoted In The U.S." ("IA 66-41") was most recently published on September 23, 2010. IA 66-41 contains a Red List, a list of importers whose products are automatically detained for FDA violations, of over 400 firms on the charge of importing misbranded unapproved new drugs. [Benjamin England](http://BenjaminEngland.com), founder of [FDAImports.com, LLC](http://FDAImports.com) and former FDA Compliance Officer and attorney, states that "This Import Alert has been expanded to include importers and products of drugs imported strictly for personal use rather than just targeting foreign shippers, which is FDA's normal M.O."

Historically, investigating and intercepting (detaining) shipments of imported personal-use drugs has been deemed an unjustified expenditure of agency resources because most personal-use drug imports are small in amount and value. FDA has stated in chapter 9, subchapter on "Coverage of Personal Importations" of the agency's *Regulatory Procedures Manual*, "Because the amount of merchandise imported into the United States in personal shipments is normally small, both in size and value, comprehensive coverage of these imports is normally not justified." [Benjamin England](http://BenjaminEngland.com) adds that "FDA's personal importation guidance, which we affectionately nicknamed the 'P.I.G.', was primarily responsible for the explosive growth over the last two decades in foreign online pharmacies. Apparently the pig has grown too fat for even FDA's liking so the agency is taking another track by going after the US importers now listed on IA 66-41."

There are only two exceptions to importing unapproved drugs into United State Commerce. As IA 66-41 clearly states, only persons who began treatment with unapproved drugs in a country other than the US and intend to continue treatment upon entering the US may be permitted to import an unapproved drug under the policy. Additionally, any individual (as opposed to a company) who made their own arrangements for obtaining the unapproved drug from foreign sources may be considered for permission to import.

On the other hand, if there is any evidence that the product has been promoted for use in the U.S. it is likely to be considered for detention. "These promotions may take place in any form," says

[Mr. England](#), “such as direct mail solicitation, internet advertisements, press releases, or those incessant spam emails you and I keep getting in our email in-boxes. Quite frankly, I blame FDA for all that spam email. But for the fattening of the P.I.G. over the decades, a multi-billion dollar industry would have not blossomed as it has.”

If you have asked ‘How do I proceed if I need to import an unapproved drug to the United States for personal medical use?’ or ‘What do I do if my company has been wrongly singled out?’ The answer is simple. Call [FDAImports.com, LLC](#), a consulting firm which is expert in Food and Drug Law compliance. It may be necessary to provide certain pieces of specific evidence to bring a detained shipment within the scope of FDA's policy. There are also options for obtaining a compassionate investigational new drug (IND) exemption in the absence of an FDA approved New Drug Application (“NDA”). Sometimes we can help identify whether a foreign version of an FDA-approved drug is actually admissible into the U.S. FDAImports.com specializes in all matters related to FDA compliance and can show you ‘the way through’.