

## 2004N-0115 - Prescription Drug Importation; Public Meeting

FDA Comment Number : EC46

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Organization : California Pharmacists Association

Drug Association

Category :

Issue Areas/Comments

FDA's Ability to Assure

Safety

7. Should FDA examine all imports, or should a sampling method, along with testing, be used to assure safety?

It is NOT a matter of peeking at the boxes of imports ... rather, the FDA must be at the manufacturing sites physically reviewing and monitoring the production in accord with the GMP standards that are in place with domestic manufacturers when their production lines are producing for domestic use.

1. What should FDA do to assure safety of imported products?

The FDA ought to implement the "pedigree requirement" that was MANDATED by law in 1988 (sixteen years ago!).

**Impact of Unapproved Drugs:**

2. What are the safety concerns posed by these products?

Parcels with drug products are routinely identified as non-FDA approved substances which are up to 88% noncompliant with subpotent, superpotent, expired, mislabeled, counterfeit, or otherwise noncompliant. Virtually ALL violate the FDA laws on importation of drug products into the US.

3. What evidence exists to substantiate these concerns?

The evidence of these problems is well documented in the records of the FDA and other federal agencies such as the FTC and DEA.

4. Can they be quantified?

The same records mentioned in answer to item #3 quantifies the problem.

1: What is the scope and volume of unapproved drugs entering the United States through mail shipments and at border crossings?

There are 13 USPS sites for receiving foreign parcels in the US. JFK Airport Customs advise that 40,000 packages are received daily, of which about 500+ parcels from "countries of interest" are reviewed. The staff available to do this are 6 FDA staff members. Virtually NO packages are actually detained due to the complications of doing so. The situation at the other 12 sites is similar.

5. What is the scope and volume of FDA-approved drugs commercially available in other countries?

Unknown as the FDA-approval relate to US commercial availability, not foreign availability. Having said this, the FDA approval process is recognised as the "gold standard" of quality worldwide.

**Regulation by Foreign Health**

## Agencies

25. What protections do other countries have in place to ensure the safety of drugs that are exported or transshipped from their country to the United States?

None of which I am aware. Health Canada, for example, has publicly declared that they "cannot and will not" guarantee the quality and safety of drug products imported into Canada for export to the US.