

Physician Responsibility

Physicians who:

Prescribe or use cosmetic
injectables,

Or allow cosmetic injectable
treatments in any practice or
business owned, operated or
advised by the physician

Are responsible and liable for
the use of these products.



FDA Approved Injectables

**Physicians are responsible
for:**

Knowledge of approved uses

Understanding what
constitutes an off-label use

Clearly identify the difference
to patients

Maintaining records of all
products uses and effects



Non-FDA Approved Products

Imported injectables are illegal, even if the product is identical to a U.S. FDA approved product

Injectables are illegal if sold by anyone other than the original manufacturer

Canadian and off-shore purchases are examples of illegal importation



Use of Non-FDA Approved Products

Illegal importation can result in:

- FDA or Court injunction
- Seizure of product
- Criminal monetary penalties and/or imprisonment
- State medical board licensure disciplinary action

Use of Non-FDA Approved Products

Illegal importation may result in:

- No indemnity by an insurance carrier in the event of alleged malpractice
- The inability to obtain future malpractice insurance



Illegal Importation

- Avoid purchasing from websites, fax blasts, and spam email
- Look for claims “justifying” or “explaining” how the product is genuine, and how the product may be obtained for personal importation
- Look for claims that a prescription is not required



Personal Use is NOT a Defense

- Note: FDA has specifically stated that virtually all products imported for personal use into the U.S. violate Federal law because they are not approved, labeled incorrectly, or dispensed without a valid prescription