



MASTER CUSTOMS SPECIALIST (MCS) COURSE

Module 15: Food and Drug Administration (FDA) | Quiz

- 1) **Some CBP personnel have been formally commissioned and specially trained to conduct cargo examinations under the Bioterrorism Act and to hold shipments.**
 - True
 - False

- 2) **The FDA requires a U.S. Agent to be designated with which registration(s)?**
 - A) Foreign Food Facilities
 - B) Foreign Cosmetics Facilities
 - C) Foreign Drug Establishments
 - D) A and B only

- 3) **The FDA requires a Foreign Supplier Verification Program for medical devices.**
 - True
 - False

- 4) **If an individual imports an unapproved drug to continue treatment started outside the U.S. for a condition for which there is no FDA approved treatment, the FDA has issued guidance to refrain from taking action against them. This guidance applies under which of the following conditions?**
 - The product does not represent an unreasonable risk
 - The individual affirms in writing that the treatment is for his own use
 - The treatment is not available domestically
 - All of the above
 - None of the above

- 5) **Biological products are loosely regulated.**
 - True
 - False



6) Which class of medical device represents the highest risk?

- Class I
- Class II
- Class III
- Class IV

7) Which of the following emits radiation?

- X-ray
- Microwave
- Hearing Aid
- Remote control
- All of the above

8) Imports of electronic products considered to be radiation emitting devices require the completion of FDA Form 2877.

- True
- False

9) Cosmetics may sometimes be considered drugs.

- True
- False

10) An importer can petition the FDA to allow them to recondition a product if it does not meet import requirements.

- True
- False