

1. MC A client expresses concerns about his newly prescribed medication. The nurse explains that the safety and effectiveness of the medication has been proven, according to the statutes of which law?

- A. Pure Food and Drug Act
- B.* Food, Drug, and Cosmetic Act
- C. FDA Modernization Act
- D. Public Health Service Act

2. MC During an immunization clinic, parents of a child ask the nurse about a recent recall of a vaccine. The nurse explains that the FDA has the ability to recall biologics by the authorization of what piece of legislation?

- A.* Childhood Vaccine Act
- B. Public Health Service Act
- C. Biologics Control Act
- D. Sherley Amendment

3. SA Arrange the four stages of approval for therapeutic and biologic drugs in the order they are completed (number the steps from 1 to 4):

- 1. clinical investigation
- 2. submission of new drug application
- 3. preclinical investigation
- 4. postmarketing studies

Answer: 2,3,1,4

Type: SA

4. MC The nurse is aware of the increased potential for adverse drug-drug and drug-herbal interactions and explains this to the client in the following statement:

- A. "The restrictions placed by the FDA are more strict."
- B. "People are using more herbs, so the risk for interaction is greater."
- C. "Managed care has made a greater number of drugs available to the consumer."
- D.* "Drugs are being developed at a faster rate than their risk can be assessed."

5. MC A public health nurse is seeking information on bioterrorist agents to present education regarding security and defense in case of attack. An appropriate resource to use would be which of the following?

- A. U.S. Armed Forces
- B. FEMA
- C.* U.S. Department of Homeland Security
- D. U.S. Army National Guard

6. MC A client asks the nurse about the safety of medications from Canadian pharmacies. The nurse responds that drugs sold in Canada:

- A. are governed by that country.
- B. are not safe.
- C. are the same as those sold in the United States.
- D.* must be marketed with a NOC and DIN.

7. MC Therapeutic drugs are sometimes classified on the basis of how they are produced. Insulin would fall into which category?

- A. alternative therapy
- B. natural therapy
- C. traditional therapeutic drug
- D.* biologics

8. MC Drugs that demonstrate wide margins of safety and are used over long periods of time are often times switched from:

- A.* prescription only to over the counter drugs.
- B. traditional drug therapy classification to biologics classification.
- C. one classification to a lower, less restrictive one.
- D. therapeutic to effective.

9. MC A client has been selected as a participant in the approval process of a particular drug. The client's dose and any effects from the medication are being monitored. The phase of drug approval that this client is participating in is the:

- A. postmarketing study.
- B. postclinical investigation.
- C.* clinical phase trial.
- D. preclinical investigation.

10. MC A certain drug, prescribed for treatment of a particular condition, is found to be beneficial in treating a different problem. Which legislation allows drug companies to share this type of information with healthcare practitioners?

- A. Therapeutic Products Programme
- B.* Prescription Drug User Fee Act
- C. Food and Drugs Act
- D. Health Products and Food Branch