

Name: _____ Date: _____

1. Food Drug and Cosmetic Act (1938) followed the fatal poisoning by
 - A) sulfanilamide.
 - B) thalidomide.
 - C) penicillin.
 - D) acetaminophen.

2. The _____ defines which drugs require a prescription.
 - A) Food and Drug Act (1906)
 - B) Food Drug and Cosmetic Act (1938)
 - C) Durham-Humphrey Amendment (1951)
 - D) Kefauver-Harris Amendment (1962)

3. The DEA is a division of the
 - A) FDA.
 - B) HCFA.
 - C) Justice Department.
 - D) CMS.

4. It is the responsibility of _____ to provide proof that a drug is safe and effective.
 - A) the FDA
 - B) the manufacturer
 - C) the DEA
 - D) the CDER

5. An inactive substance given in place of a medication is a/an
 - A) element.
 - B) compound.
 - C) placebo.
 - D) generic.

6. The main purpose of phase I clinical drug testing is
 - A) safety.
 - B) efficacy.
 - C) dosage range.
 - D) interactions.

7. The largest number of patients are in _____ of clinical drug testing.
- A) phase I
 - B) phase II
 - C) phase III
 - D) IND
8. The first set of numbers in the NDC indicates
- A) the drug name, strength and dosage form.
 - B) the package size.
 - C) the manufacturer.
 - D) the patent year.
9. Drugs in DEA Schedule I have no accepted medical use.
- A) True
 - B) False
10. The most serious classification for a drug recall is Class ____:
- A) I
 - B) II
 - C) III
 - D) IV
11. Which phase of drug development uses volunteers rather than patients?
- A) Preclinical/Discovery
 - B) Phase I
 - C) Phase II
 - D) Phase III
12. Before drugs studies can be started in humans, which of the following must filed with the FDA?
- A) DEA
 - B) NDA
 - C) ANDA
 - D) IND

13. In a double-blind study who knows what treatment was administered to the patient/volunteer?

- A) Doctor
- B) Patient
- C) Nursing staff
- D) Company statistician

14. Phase IV studies are started:

- A) Upon completion of Phase III
- B) When the NDA is filed with the FDA
- C) After the NDA is approved by the FDA
- D) There is no Phase IV

Bonus Questions .

For each bonus question please give the generic name and use. - 2 points for each question answered correctly

1. Glucophage

2. Xanax

3. Synthroid

4. Lipitor

5. Amoxil

Answer Key

1. A
2. C
3. C
4. B
5. C
6. A
7. C
8. C
9. A
10. A
11. B
12. D
13. D
14. C

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