Name: _____ Class: _____ Date: _____

Chapter 1 Consumer Safety and Drug Regulations

Match each name to the definition listed below.

a. Standards
b. Controlled (schedule) drug
c. Legend drug
d. FDA
e. DEA

QUESTION TYPE: Matching
HAS VARIABLES: False
DATE CREATED: 12/4/2017 12:15 AM
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1. Requires a prescription but not a DEA number
ANSWER: c
POINTS: 1

2. These were established by the 1906 Pure Food and Drug Act
ANSWER: a
POINTS: 1

3. Requires a prescription and DEA number
ANSWER: b
POINTS: 1

4. Enforcement agency established by the 1970 Controlled Substances Act
ANSWER: e
POINTS: 1

5. Approval agency established by the 1938 Federal Food, Drug and Cosmetic Act
ANSWER: d
POINTS: 1

Match each example to the names listed below.

a. Orphan drug
b. Drug standards
c. NDC
d. USP/NF
e. OTC

QUESTION TYPE: Matching
HAS VARIABLES: False
DATE CREATED: 12/4/2017 12:18 AM
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6. Uniform strength, purity and quality
ANSWER: b
POINTS: 1

7. Drug that treats a disease affecting a very small number of people
ANSWER: a
POINTS: 1

8. Directory listing drugs by manufacturer and packaging type(s).
ANSWER: c
POINTS: 1

9. Directory listing of officially approved drugs (was originally two references)
ANSWER: d
POINTS: 1

10. These drugs require no prescription.
ANSWER: e
POINTS: 1

11. The pharmaceutical manufacturer has the authority to add additional active ingredients to a previously approved pharmaceutical product.
ANSWER: False - According to the 1938 Federal Food, Drug, and Cosmetic Act and Amendments of 1951 and 1962, all labels must be accurate and include a listing of all active and inactive ingredients.
POINTS: 1
QUESTION TYPE: Modified True / False
HAS VARIABLES: False
DATE CREATED: 12/4/2017 12:23 AM
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12. Drug strength may vary with each lot number of a medication.
ANSWER: False - The 1906 Pure Food and Drug Act established that all drugs marketed in the United States meet minimal standards of uniform strength, purity, and quality.
POINTS: 1
QUESTION TYPE: Modified True / False
HAS VARIABLES: False

Chapter 1 Consumer Safety and Drug Regulations

S:
DATE CREATED: 12/4/2017 12:21 AM
D:
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ED:

13. The Pure Food and Drug Act of 1906 established drug standards and official drug references.

ANSWER:	True
POINTS:	1
QUESTION TYPE:	Modified True / False
HAS VARIABLES:	False
DATE CREATED:	12/4/2017 12:23 AM
DATE MODIFIED:	12/4/2017 12:23 AM

14. The 1906 Pure Food and Drug Act established consumer protections to prevent the inclusion of "dangerous ingredients" without the knowledge of the consumer.

ANSWER:	True
POINTS:	1
QUESTION TYPE:	Modified True / False
HAS VARIABLES:	False
DATE CREATED:	12/4/2017 12:24 AM
DATE MODIFIED:	12/4/2017 12:24 AM

15. Medication labels need only include the trade name of the drug.

ANSWER: False - Labels must include a listing of all active and inactive ingredients, warning labels on certain preparations, and generic names for the medication
POINTS: 1
QUESTION TYPE: Modified True / False
HAS VARIABLES: False
DATE CREATED: 12/4/2017 12:24 AM
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16. The prescriber of the medication is the only health care professional who is responsible for being aware of new medications, laws, and restrictions.

ANSWER: False - The health care worker involved in administration of a medication also bears the responsibility of being aware of the laws and restrictions pertinent to that medication.
POINTS: 1

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QUESTION TYPE: Modified True / False
HAS VARIABLES: False
DATE CREATED: 12/4/2017 12:25 AM
DATE MODIFIED: 12/4/2017 12:25 AM

17. A double-locked system is the recommended method for maintaining security of controlled substances.

ANSWER: True
POINTS: 1
QUESTION TYPE: Modified True / False
HAS VARIABLES: False
DATE CREATED: 12/4/2017 12:25 AM
DATE MODIFIED: 12/4/2017 12:26 AM

18. Health care workers are responsible for maintaining records of all controlled substances received, dispensed, and destroyed.

a. True
b. False

ANSWER: True
POINTS: 1
QUESTION TYPE: True / False
HAS VARIABLES: False
DATE CREATED: 12/4/2017 12:28 AM
DATE MODIFIED: 12/4/2017 12:28 AM

19. Controlled substance records are to be kept for 10 years.

ANSWER: False - Records for the previous 2 years must be available at all times for inspection.
POINTS: 1
QUESTION TYPE: Modified True / False
HAS VARIABLES: False
DATE CREATED: 12/4/2017 12:26 AM
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20. The NDC contains the manufacturer, product, and package information for all commercially available products.

a. True
b. False

ANSWER: True

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POINTS: 1
QUESTION TYPE: True / False
HAS VARIABLES: False
DATE CREATED: 12/4/2017 12:27 AM
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21. Identify the drug standard in the following list.

a. Color
b. Strength
c. Shape
d. Taste

ANSWER: b
FEEDBACK:
a. Color is not a standard.
b. Correct!
c. Shape is not a standard.
d. Taste is not a standard.

POINTS: 1
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
DATE CREATED: 12/4/2017 1:27 AM
DATE MODIFIED: 12/4/2017 1:42 AM

22. The risk of death from the use of *street drugs* versus *prescription medications* is mostly due to___.

a. a lack of control over quality, purity, and strength makes street drugs dangerous
b. the risk is the same for both sources of the same substance
c. street drugs are approved for use
d. the need for a prescription makes drugs hard to obtain

ANSWER: a
FEEDBACK:
a. Correct!
b. The lack of enforcement of drug standards in illegal street drugs poses a significant danger for the consumer.
c. The exact composition of a street drug is unknown, and it may contain dangerous contaminants or undisclosed additional drugs.
d. Street drugs are illegal.

POINTS: 1
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
DATE CREATED: 12/4/2017 1:27 AM

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D:
DATE MODIFI 12/4/2017 1:43 AM
ED:

23. Drug standards regulate drug manufacture so that medications of the same name will be of the same ____.

a. strength, purity, and quality
b. shape, color, and taste
c. purity, shape, and color
d. quality, color, and smell

ANSWER: a
FEEDBACK:
a. Correct!
b. Standards do not include shape, color or taste.
c. Standards do not include shape or color.
d. Standards do not include color or smell.

POINTS: 1
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
DATE CREATED: 12/4/2017 1:27 AM
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24. The 1906 Pure Food and Drug Act includes which of the following provisions?

a. Regulation of drugs sold in the United States and Canada
b. Requires labeling to indicate if a medication contained a “dangerous ingredient”
c. Regulates illicit (illegal) drugs
d. Requires information regarding medications to be handed down from one practitioner to the next

ANSWER: b
FEEDBACK:
a. The Pure Food and Drug Act regulates ALL drugs MARKETED in the United States. If a drug is manufactured in Canada, it must meet USFDA requirements to be marketed here.
b. Correct!
c. Illicit drugs are not regulated.
d. The Pure Food and Drug Act established two references of officially approved drugs, the USP and the NF.

POINTS: 1
QUESTION TY Multiple Choice
PE:
HAS VARIABLE False
S:
DATE CREATE 12/4/2017 1:27 AM
D:
DATE MODIFI 12/4/2017 1:44 AM

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ED:

25. The Pure Food and Drug Act of 1906 was formulated _____.
    a. to control use of drugs being abused by society
    b. as the first government attempt to establish consumer protection in the manufacture of drugs and foods
    c. in order to make drug manufacturing profitable for the drug companies
    d. as a means to identify addicting or abused drugs

ANSWER: b

FEEDBACK:
    a. This applies to the Controlled Substances Act of 1970.
    b. Correct!
    c. The Pure Food and Drug Act was in answer to a need for consumer safety.
    d. This applies to the Controlled Substances Act of 1970.

POINTS: 1
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
DATE CREATED: 12/4/2017 1:27 AM
DATE MODIFIED: 12/4/2017 1:45 AM

26. Which act required that drug preparations containing morphine have a label indicating the presence of morphine?
    a. Federal Food, Drug, and Cosmetic Act of 1938
    b. Federal Food, Drug, and Cosmetic Act Amendment of 1965
    c. Controlled Substances Act of 1970
    d. Pure Food and Drug Act of 1906

ANSWER: d

FEEDBACK:
    a. This act formed the FDA.
    b. There was no amendment in 1965.
    c. The 1970 Controlled Substances Act identified schedules of abused or additive drugs.
    d. Correct!

POINTS: 1
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
DATE CREATED: 12/4/2017 1:27 AM
DATE MODIFIED: 12/4/2017 1:45 AM

27. Identify a provision of the Federal Food, Drug, and Cosmetic Act and its Amendments _____.
    a. new products are required to be approved by the Food and Drug Administration
    b. defined schedules for substances that require specific controls
    c. it set limitations on the use of prescriptions
    d. established USP

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ANSWER: a

FEEDBACK:
a. Correct!
b. This response applies to the 1970 Controlled Substances Act.
c. Prescription limitations were defined by the 1970 Controlled Substances Act.
d. USP was established by the 1906 Pure Food and Drug Act.

POINTS: 1
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
DATE CREATED: 12/4/2017 1:27 AM
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28. What drugs are referred to as "legend" drugs?
a. Drugs that work so well they become "legendary."
b. Drugs that have been available for over 100 years.
c. Drugs that must carry the legend "Caution—federal law prohibits dispensing without a prescription."
d. Drugs that are mentioned in urban legends.

ANSWER: c

FEEDBACK:
a. Legend drugs require a prescription from a provider.
b. Legend drugs may be old or new and require a prescription.
c. Correct!
d. Legend drugs require a prescription from a provider

POINTS: 1
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
DATE CREATED: 12/4/2017 1:27 AM
DATE MODIFIED: 12/4/2017 1:47 AM

29. The Food and Drug Administration was created to _____.
a. oversee testing of all proposed new drugs prior to release into the U.S. market
b. inspect plants where food, drugs, medical devices, and cosmetics are made
c. remove unsafe drugs from the market
d. All of the above.

ANSWER: d

FEEDBACK:
a. This is a responsibility of the FDA, but not the only thing the FDA does.
b. This is a responsibility of the FDA, but not the only thing the FDA does.
c. This is a responsibility of the FDA, but not the only thing the FDA does.
d. Correct! All the answers are roles of the FDA.

POINTS: 1

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QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
DATE CREATED: 12/4/2017 1:27 AM
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30. The USP/NF (U.S. Pharmacopeia/National Formulary) was established to _____.
    a. provide a reference for all officially approved medications
    b. legalize the manufacture of medications.
    c. give the public the information needed to safely make their own drugs.
    d. All of the above.

ANSWER: a
FEEDBACK:
    a. Correct!
    b. The USP/NF is a reference with no approval authority.
    c. The USP/NF is a reference.
    d. A is the only correct choice.

POINTS: 1
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
DATE CREATED: 12/4/2017 1:27 AM
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31. USP is the official abbreviation for _____.
    a. U.S. Post office
    b. U.S. Patrol
    c. U.S. Police
    d. U.S. Pharmacopoeia

ANSWER: d
FEEDBACK:
    a. U.S. Post office provides mail services, not pharmacy services.
    b. This is not a pharmacy-related agency.
    c. Remember, the abbreviation would be related to pharmacy.
    d. Correct! United States Pharmacopoeia.

POINTS: 1
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
DATE CREATED: 12/4/2017 1:27 AM
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32. NF is the official abbreviation for _____.
    a. National Football

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b. National Fortress
c. National Food
d. National Formulary

ANSWER: d

FEEDBACK:
a. Not football, remember this is a related to pharmacology.
b. Not fortress, it is something to do with pharmacology.
c. Not food, something related to pharmacy.
d. Correct! National Formulary

POINTS: 1
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
DATE CREATED: 12/4/2017 1:27 AM
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33. Prior to the 1906 establishment of the U.S. Pharmacopeia, drug information was related by _____.
a. the Internet
b. encyclopedias
c. passing to the next generation
d. schools of medicine and pharmacology

ANSWER: c

FEEDBACK:
a. There was no Internet in 1906, and the first drug act was passed this year.
b. Drug information for medical use is not provided in an encyclopedia.
c. Correct! Information was passed from one person to another.
d. There were no drug references available and teaching was very informal prior to 1906.

POINTS: 1
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
DATE CREATED: 12/4/2017 1:27 AM
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34. Which bureau of the Department of Justice was established by the Controlled Substances Act of 1970?
a. USP
b. DEA
c. FDA
d. NF

ANSWER: b

FEEDBACK:
a. U.S. Pharmacopeia
b. Correct! Drug Enforcement Agency

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c. Food and Drug Administration
d. National Formulary

POINTS: 1
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
DATE CREATED: 12/4/2017 1:27 AM
DATE MODIFIED: 12/4/2017 2:17 AM

35. The Controlled Substances Act of 1970 set much tighter controls on a specific group of drugs that are _____.
a. at risk of being abused by society
b. listed in the USP/NF
c. those that contain herbal components
d. available over the counter

ANSWER: a
FEEDBACK:
a. Correct!
b. This refers to the 1906 Pure Food and Drug Act.
c. The FDA does not approve dietary or herbal supplements.
d. OTCs were outlined in the 1938 Federal Food, Drug, and Cosmetic Act.

POINTS: 1
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
DATE CREATED: 12/4/2017 1:27 AM
DATE MODIFIED: 12/4/2017 2:18 AM

36. The Controlled Substances Act may limit _____.
a. the number of refills that can be filled in a 6-month time frame
b. at which pharmacies the patient may get the prescription filled
c. the level of pain control to be maintained
d. how the patient may maintain or store the medication

ANSWER: a
FEEDBACK:
a. Correct!
b. The government does not limit where prescriptions may be filled.
c. The Act does not address pain control.
d. The government does not regulate where private citizens may keep their medications.

POINTS: 1
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
DATE CREATED: 12/4/2017 1:27 AM

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37. The Controlled Substances Act sets tighter controls on _____.
    a. common analgesics such as Tylenol or aspirin
    b. depressants, stimulants, psychedelics, narcotics, and anabolic steroids
    c. antibiotics, diuretics, antihypertensives, and diabetic medications
    d. common cold/allergy medications

ANSWER: b

FEEDBACK:
a. Tylenol and aspirin are provided over the counter and access to them is not regulated.
b. Correct!
c. These are prescription medications that are not considered to be at risk for abuse.
d. These currently remain as over-the-counter medications but more controls are being applied.

POINTS: 1
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
DATE CREATED: 12/4/2017 1:27 AM
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38. Which of the following is required to have a DEA number?
    a. The provider writing the prescription
    b. The person receiving the prescription
    c. All providers working in the physician's office or clinic
    d. All providers working in the pharmacy

ANSWER: a

FEEDBACK:
a. Correct!
b. People receiving the prescription do not need a DEA number.
c. Only the prescriber needs a DEA number.
d. Only the pharmacist needs a DEA number.

POINTS: 1
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
DATE CREATED: 12/4/2017 1:27 AM
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39. Professionals needing a DEA number are _____.
    a. registered nurses (RNs), licensed (vocational) nurses (LPN/LVNs), and certified medication assistants (CMAs)
    b. pharmacists, physicians, and veterinarians

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c. clients who have a professional license

d. administrators of nursing care facilities, acute care hospitals, and home health care associations

ANSWER: b

FEEDBACK:

a. Health care providers administering medications do not need a DEA number.

b. Correct!

c. No client needs a DEA number, regardless of occupation.

d. Administrators of institutions do not need DEA numbers.

POINTS: 1
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
DATE CREATED: 12/4/2017 1:27 AM
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40. DEA numbers appear on the _____.

a. prescriber's professional license

b. prescription for a controlled substance

c. medication bottle that contains the controlled substance

d. receipt for the medication

ANSWER: b

FEEDBACK:

a. The DEA number does not appear on the professional's license.

b. Correct!

c. The DEA number does not appear on the medication container.

d. The DEA number does not appear on the receipt.

POINTS: 1
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
DATE CREATED: 12/4/2017 1:27 AM
DATE MODIFIED: 12/4/2017 2:23 AM

41. A DEA number represents _____.

a. the number of times the DEA has cited the person

b. the phone number for the local DEA office

c. registration with the Drug Enforcement Agency

d. the prescriber's professional state license number

ANSWER: c

FEEDBACK:

a. DEA number does not provide citation information

b. DEA number is the individual's registration number assigned by the Drug Enforcement Agency

c. Correct!

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d. State licensure does not include DEA number

POINTS: 1
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
DATE CREATED: 12/4/2017 1:27 AM
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42. Agencies/persons that are required to have a DEA number are _____.

a. acute care hospitals and nursing homes
b. pharmacies, grocery stores, and convenience stores
c. drug manufacturers and packaging facilities, pharmacists, and physicians
d. schools of nursing, medical assisting, and radiology

ANSWER: c
FEEDBACK:

a. The DEA does not regulate hospitals and nursing homes.
b. The DEA does not regulate grocery stores or convenience stores.
c. Correct!
d. The DEA does not regulate schools.

POINTS: 1
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
DATE CREATED: 12/4/2017 1:27 AM
DATE MODIFIED: 12/4/2017 2:24 AM

43. The schedule of controlled substances that has the highest risk of abuse potential is _____.

a. Schedule C 2
b. Schedule C 3
c. Schedule C 4
d. Schedule C 5

ANSWER: a
FEEDBACK:

a. Correct!
b. The lower the number the higher potential for abuse.
c. The lower the number the higher potential for abuse.
d. The lower the number the higher potential for abuse.

POINTS: 1
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
DATE CREATED: 12/4/2017 1:27 AM
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44. Drugs listed in Schedule 1 of Controlled Substances _____.

a. are not approved for medical use in the United States
b. may be refilled up to five times in 6 months
c. may have prescriptions phoned in by health care workers
d. have low abuse potential compared to other schedules

ANSWER: a

FEEDBACK:

a. Correct!
b. Schedule 1 drugs are not approved for medical use in the United States.
c. Schedule 1 drugs are not approved for medical use in the United States.
d. Schedule 1 drugs have the highest risk of abuse or addiction.

POINTS: 1
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
DATE CREATED: 12/4/2017 1:27 AM
DATE MODIFIED: 12/4/2017 2:27 AM

45. Prescriptions of the controlled substances listed in these schedules have restrictions about phoning them into the pharmacy _____.

a. Schedule 1
b. Schedule 2
c. Schedule 3
d. All of the above.

ANSWER: d

FEEDBACK:

a. Schedule 1 drugs are illegal for use and are not available to be prescribed in any fashion in the United States.
b. Schedule 2 drugs may not be called in to the pharmacy unless in cases of emergency, and then only by a physician. The call must be followed by a handwritten prescription within 72 hours.
c. Schedule 3 drugs may be phoned in by a physician only.
d. Correct!

POINTS: 1
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
DATE CREATED: 12/4/2017 1:27 AM
DATE MODIFIED: 12/4/2017 2:28 AM

46. Prescriptions of the controlled substances listed in which of these schedules MAY be called into the pharmacy by

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health care workers other than the prescriber _____.

a. Schedules 1 and 2 only
b. Schedules 2 through 4
c. Schedules 4 and 5 only
d. Schedules 1 through 3

ANSWER: c

FEEDBACK:
a. Schedule 1 is not approved for medical use in the United States. Schedule 2 may be phoned into the pharmacy by a physician in an emergency only, followed by a written prescription within 72 hours.
b. Schedule 2 may only be phoned in by the physician in an emergency. Schedule 3 may be phoned in by the physician only. Schedules 4 and 5 may be phoned in by an office health care worker.
c. Correct!
d. Schedule 3 may be phoned in by the physician only.

POINTS: 1

QUESTION TYPE: Multiple Choice

HAS VARIABLES: False

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47. Prescriptions of the controlled substances listed in these schedules may be refilled up to five times in 6 months _____.

a. Schedules 1 and 2
b. Schedules 3 and 4
c. Schedules 3, 4, and 5
d. Schedules 1, 2, 3, 4, and 5

ANSWER: c

FEEDBACK:
a. Schedule 1 drugs are not approved for medical use in the United States. Schedule 2 drugs may not be refilled.
b. Both may be refilled five times in 6 months, but there is a more complete answer.
c. Correct!
d. Schedule 1 drugs are not approved for medical use in the United States. Schedule 2 drugs may not be refilled.

POINTS: 1

QUESTION TYPE: Multiple Choice

HAS VARIABLES: False

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DATE CREATED: 12/4/2017 1:27 AM
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48. The *least* desirable information source regarding drugs is a _____.

a. current drug reference
b. pharmacist
c. coworker
d. pharmaceutical company representative

ANSWER: c
FEEDBACK:
a. U.S. Pharmacopeia is a reliable source.
b. The pharmacist is a reliable source.
c. Correct! A coworker cannot always be considered a reliable source.
d. Pharmaceutical representatives are considered reliable sources for their products.

POINTS: 1
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
DATE CREATED: 12/4/2017 1:27 AM
DATE MODIFIED: 12/4/2017 2:31 AM

49. Which act established the USP and NF?

a. 1938 Federal Food, Drug, and Cosmetic Act
b. 1906 Pure Food and Drug Act
c. 1965 Pharmaceutical Consumer Protection Act
d. 1962 Amendment to the 1938 Federal Food, Drug, and Cosmetic Act

ANSWER: b
FEEDBACK:
a. The 1938 Federal Food, Drug, and Cosmetic Act primarily addressed prevention of tampering with products.
b. Correct!
c. The “1965 Pharmaceutical Consumer Protection Act” does not exist.
d. The 1962 Amendment to the 1938 Federal Food, Drug, and Cosmetic Act was concerned with labeling and assuring that prescription and nonprescription drugs were both effective and safe.

POINTS: 1
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
DATE CREATED: 12/4/2017 1:27 AM

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D:
DATE MODIFI 12/4/2017 2:32 AM
ED:

50. An *orphan drug* is defined as a(n) _____.

a. drug used only in children
b. drug used to treat a disease that affects only a small number of people
c. lone drug in a specific class of drugs
d. unapproved drug used to treat a rare disease

ANSWER: b

FEEDBACK:

a. Orphan drugs may treat rare diseases of any age group.
b. Correct!
c. Orphan drugs treat uncommon diseases.
d. Orphan drugs treat rare diseases and there may be exceptions regarding approval but there is a better definition for orphan drug.

POINTS: 1
QUESTION TY Multiple Choice
PE:
HAS VARIABLE False
S:
DATE CREATE 12/4/2017 1:27 AM
D:
DATE MODIFI 12/4/2017 2:32 AM
ED:

51. Which legislation provides for financial incentives to be provided to pharmaceutical companies for the development of medications that would otherwise be unprofitable because they are designed to treat diseases that affect only a small number of people?

a. 1965 Pure Food and Drug Act
b. 1938 Orphan Drug and Cosmetic Act
c. 1983 Orphan Drug Act
d. OBRA of 1990

ANSWER: c

FEEDBACK:

a. Pure Food and Drug Act was passed in 1906.
b. This act does not exist.
c. Correct!
d. This act does not exist.

POINTS: 1
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False

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52. What new requirements were mandated by the Omnibus Budget Reconciliation Act of 1990?
    a. All prescriptions are to be included as part of the permanent medical record.
    b. Over-the-counter medications are to be entered into the permanent medical record.
    c. Pharmacists are required to provide drug use review and patient counseling prior to dispensing prescriptions to patients.
    d. Both B and C are correct.
    e. All of the above.

ANSWER: d

FEEDBACK:
    a. Prescription medications were previously required to be included in the medical records.
    b. Correct, but there is a more complete answer – OBRA mandated the additional requirement of documenting over-the-counter medications and counseling to be provided by the dispensing pharmacist
    c. Correct, but there is a more complete answer – OBRA mandated the additional requirement of documenting over-the-counter medications and counseling to be provided by the dispensing pharmacist.
    d. Correct! Both B and C are new OBRA requirements.
    e. Not all answers are correct.

POINTS: 1
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
DATE CREATED: 12/4/2017 1:27 AM
DATE MODIFIED: 12/13/2017 12:44 AM

53. Once a drug or device has been approved for use in the United States, the _____.
    a. DEA may withdraw approval if a safety concern exists
    b. only action that can be taken is requirement of additional warnings to be added to the labeling and recommendation for voluntary withdrawal by the manufacturer
    c. FDA may reconsider its approval and withdraw it from the market to protect the public safety
    d. DEA may demand withdrawal from the market

ANSWER: b

FEEDBACK:
    a. The DEA is not involved in approvals or withdrawals.
    b. Correct!
    c. The FDA has the power to review and make recommendations regarding withdrawals of approved drugs, but it cannot enforce a withdrawal.
    d. Withdrawals are made voluntarily by the manufacturer based on safety reports and review.

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POINTS: 1
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
DATE CREATED: 12/4/2017 1:27 AM
DATE MODIFIED: 12/4/2017 2:36 AM

54. The National Drug Code Directory (NDC) was established in 1972 and provides the FDA with the following information for all drugs commercially distributed _____.

a. the drug name
b. packaging information
c. the manufacturer of the product
d. All of the above are included in the NDC.

ANSWER: d
FEEDBACK:
a. Drug name is included, but there is a more complete answer.
b. Packaging information is included, but there is a more complete answer.
c. Manufacturer is included as the first five digits, but there is a more complete answer.
d. Correct! The NDC has three parts: Manufacturer, product, and packaging.

POINTS: 1
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
DATE CREATED: 12/4/2017 1:27 AM
DATE MODIFIED: 12/4/2017 2:38 AM

55. The FDA needs to identify all the packaging options available for a drug, the best reference to locate this information would be _____.

a. U.S. Pharmacopoeia
b. National Drug Code Directory
c. National Formulary
d. National Drug Registration Database

ANSWER: b
FEEDBACK:
a. U.S. Pharmacopoeia would not be the best choice for packaging information.
b. Correct! Packaging information is included in the NDC Directory.
c. National Formulary would not be the best choice for packaging information.
d. This option does not exist.

POINTS: 1

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QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
DATE CREATED: 12/4/2017 1:27 AM
DATE MODIFIED: 12/4/2017 2:39 AM

56. The Sunshine Act, which is part of the Affordable Care Act, requires reporting of _____.

a. monetary payment a physician receives from a pharmaceutical representative
b. any compensation or gifts paid to physicians by pharmaceutical representatives
c. gifts worth over one-hundred dollars a physician receives from pharmaceutical representatives
d. all samples a physician receives from pharmaceutical representatives

ANSWER: b

FEEDBACK:

a. Payments must be reported but there is a more complete answer choice.
b. Correct! All forms of reward or compensation must be reported.
c. Gifts must be reported but there is a more complete answer choice.
d. The Sunshine Act requires all forms of reward or compensation be reported. Ethical dilemmas can occur when physicians are rewarded for prescribing certain medications.

POINTS: 1
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
DATE CREATED: 12/4/2017 1:27 AM
DATE MODIFIED: 12/4/2017 2:39 AM

57. Your friend, Thomas, had a serious adverse reaction to an over-the-counter medication and found that a number of other individuals had similar adverse reactions. Which agency is most likely to investigate this situation and take action if a problem is found?

a. Food and Drug Administration
b. United States Pharmacopeia
c. National Formulary Enforcement
d. Drug Enforcement Agency

ANSWER: a

FEEDBACK:

a. Correct!
b. USP is a reference only.
c. National Formulary Enforcement does not exist.
d. The DEA is not involved in monitoring adverse drug reactions for OTC products.

POINTS: 1
QUESTION TYPE: Multiple Choice

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HAS VARIABLES: False
DATE CREATED: 12/4/2017 1:27 AM
DATE MODIFIED: 12/4/2017 2:40 AM

58. Quinn hears on the news that the FDA has asked a company to withdraw a medication. Under what circumstances can the FDA do this?

a. When more effective alternatives are available
b. When it is no longer profitable
c. Never, because only the DEA can do this
d. When the benefits of a drug outweigh its risks

ANSWER: d

FEEDBACK:
a. Other drug availability would not be a reason to ask for a drug to be withdrawn from the market.
b. The FDA does not make recommendations based on profitability.
c. The DEA doesn't make these recommendations.
d. Correct! The FDA can recommend a company take a drug off the market if complications or adverse events are documented.

POINTS: 1
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
DATE CREATED: 12/4/2017 1:27 AM
DATE MODIFIED: 12/4/2017 2:41 AM

59. Ian, a registered nurse, maintains that he is not a drug abuser, so the 1970 Controlled Substances Act has no relevance for him. Is he right?

a. Yes, except that his state licensing board may place additional restrictions on him.
b. No, as long as he is careful to avoid the appearance of impropriety and is generally responsible in his all aspects of life.
c. Yes, as long as he does not abuse drugs, this act does not impact him.
d. No, because the act lays out his responsibilities with respect to record keeping and administration of controlled substances.

ANSWER: d

FEEDBACK:
a. The Controlled Substances Act is not about licensure of medical professionals.
b. All medical professionals who work with controlled substances need to know how the Controlled Substances Act applies to the drugs they administer.
c. If Ian works in a facility providing controlled substances, or works with patients they are prescribed to, he is responsible for following the guidelines.
d. Correct! As an RN, Ian is responsible for knowing the rules and laws about handling and

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administering controlled substances.

POINTS: 1

QUESTION TYPE: Multiple Choice

HAS VARIABLES: False

DATE CREATED: 12/4/2017 1:27 AM

DATE MODIFIED: 12/4/2017 2:42 AM

60. You're waiting in line at the pharmacy to get your medication, and decide to take a look at your doctor's handwriting on the prescription. You notice the phrase "DEA Number" followed by a code. What does the phrase "DEA Number" represent?

a. The code required to determine whether the drug is reimbursable
b. The physician's license number for your state
c. The drug standards met by the medication prescribed for you
d. The registration number for physicians who prescribe controlled substances

ANSWER: d

FEEDBACK:

a. DEA stands for Drug Enforcement Agency. The code is related to controlled substances prescribing not insurance reimbursement.
b. The DEA number is not the same as a physician’s licensure.
c. A DEA number is required on all schedule drug prescriptions.
d. Correct! Physicians, pharmacists, physician’s assistants, nurse practitioners, dentists, and veterinarians who prescribe controlled substances must have a DEA number.

POINTS: 1

QUESTION TYPE: Multiple Choice

HAS VARIABLES: False

DATE CREATED: 12/4/2017 1:28 AM

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