Name: _____ Class: _____ Date: _____

02 Veterinary Drug Development and Control

1. How long does it take on average for testing before a new veterinary drug appears on the market?

a. One year
b. Three years
c. Five years
d. Seven years

ANSWER: d
RATIONALE: It can take an average of seven years of testing and millions of dollars in funding to bring a new veterinary drug to market. See The Stages of Veterinary Drug Development.
POINTS: 1
DIFFICULTY: Easy
REFERENCES: Stages of Veterinary Drug Development
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
LEARNING OBJECTIVES: ROMI02.01 - Outline the stages of drug development in the United States.
KEYWORDS: Bloom's: Remember
DATE CREATED: 11/22/2019 8:07 AM
DATE MODIFIED: 11/22/2019 8:10 AM

2. During which stage of drug development is a drug approved or rejected?

a. Stage I
b. Stage II
c. Stage III
d. Stage IV

ANSWER: c
RATIONALE: During submission and review of the New Animal and Drug Application (NADA) which is Stage III, approval or rejection of the drug based on clinical trial data takes place. See The Stages of Veterinary Drug Development.
POINTS: 1
DIFFICULTY: Easy
REFERENCES: The Stages of Veterinary Drug Development
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
LEARNING OBJECTIVES: ROMI02.01 - Outline the stages of drug development in the United States.
KEYWORDS: Bloom's: Remember
DATE CREATED: 11/22/2019 8:11 AM
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3. Which regulatory agency develops new uses of existing pesticides?

a. USDA
b. EPA

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c. FDA
d. DEA

ANSWER: b
RATIONALE: The EPA develops new uses of existing pesticides. See The Stages of Veterinary Drug Development.
POINTS: 1
DIFFICULTY: Easy
REFERENCES: The Stages of Veterinary Drug Development
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
LEARNING OBJECTIVES: ROMI02.01 - Outline the stages of drug development in the United States.
KEYWORDS: Bloom's: Remember
DATE CREATED: 11/22/2019 8:13 AM
DATE MODIFIED: 11/22/2019 8:14 AM

4. When can preclinical studies begin?

a. Stage I
b. Stage II
c. Stage III
d. Stage IV

ANSWER: b
RATIONALE: Preclinical studies begin in Stage II if the preliminary studies produce favorable results. See The Stages of Veterinary Drug Development.
POINTS: 1
DIFFICULTY: Easy
REFERENCES: The Stages of Veterinary Drug Development
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
LEARNING OBJECTIVES: ROMI02.01 - Outline the stages of drug development in the United States.
KEYWORDS: Bloom's: Remember
DATE CREATED: 11/22/2019 8:14 AM
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5. What is another name for stability studies?

a. Shelf life studies
b. Clinical trials
c. Post-approval monitoring
d. Surveillance studies

ANSWER: a

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RATIONALE: Studies on shelf life (stability studies) show how long a drug in storage remains stable and effective for use. See The Stages of Veterinary Drug Development.
POINTS: 1
DIFFICULTY: Easy
REFERENCES: The Stages of Veterinary Drug Development
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
LEARNING OBJECTIVES: ROMI02.01 - Outline the stages of drug development in the United States.
KEYWORDS: Bloom's: Remember
DATE CREATED: 11/22/2019 8:16 AM
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6. What test is done to determine the dosage at which a drug induces organ or tissue damage resulting in permanent injury or death?

a. Margin of safety
b. Therapeutic indexing
c. Systems-oriented screening
d. Toxicity evaluation

ANSWER: d
RATIONALE: The preclinical toxicity evaluation is done to determine the dosage at which a drug induces organ or tissue damage that may result in permanent injury or death. See Safety and Effectiveness Evaluation.
POINTS: 1
DIFFICULTY: Easy
REFERENCES: Safety and Effectiveness Evaluation
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
LEARNING OBJECTIVES: ROMI02.02 - Outline how the Food and Drug Administration (FDA) tests the safety of drugs.
KEYWORDS: Bloom's: Remember
DATE CREATED: 11/22/2019 8:18 AM
DATE MODIFIED: 11/22/2019 8:23 AM

7. Which agency requires that all drugs be tested for adverse effects before approval?

a. USDA
b. EPA
c. FDA
d. DEA

ANSWER: c
RATIONALE: All drugs that are approved by the FDA must be tested to determine if they are effective and what adverse effects they may cause at therapeutic dosages. See Safety and Effectiveness Evaluation.

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POINTS: 1
DIFFICULTY: Easy
REFERENCES: Safety and Effectiveness Evaluation
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
LEARNING OBJECTIVES: ROMI02.02 - Outline how the Food and Drug Administration (FDA) tests the safety of drugs.
KEYWORDS: Bloom's: Remember
DATE CREATED: 11/22/2019 8:23 AM
DATE MODIFIED: 11/22/2019 8:25 AM

8. If a serious adverse reaction occurs on a _____ then the manufacturer will most likely terminate drug testing.

a. special test
b. short-term toxicity test
c. reproductive test
d. long-term test

ANSWER: b
RATIONALE: A short-term toxicity test that produces serious adverse reactions may prompt the manufacturer to terminate the drug testing. See Safety and Effectiveness Evaluation.
POINTS: 1
DIFFICULTY: Easy
REFERENCES: Safety and Effectiveness Evaluation
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
LEARNING OBJECTIVES: ROMI02.02 - Outline how the Food and Drug Administration (FDA) tests the safety of drugs.
KEYWORDS: Bloom's: Remember
DATE CREATED: 11/22/2019 8:25 AM
DATE MODIFIED: 11/22/2019 8:38 AM

9. If a manufacturer wants to see if a drug causes cancerous tumors, which test would be conducted?

a. Carcinogenicity test
b. Special test
c. Reproductive test
d. Teratogenicity test

ANSWER: a
RATIONALE: Carcinogenicity tests check to see if a drug causes cancerous tumors. See Safety and Effectiveness Evaluation.
POINTS: 1
DIFFICULTY: Easy
REFERENCES: Safety and Effectiveness Evaluation
QUESTION TYPE: Multiple Choice

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HAS VARIABLES: False
LEARNING OBJECTIVES: ROMI02.02 - Outline how the Food and Drug Administration (FDA) tests the safety of drugs.
KEYWORDS: Bloom's: Remember
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10. Which of the following statements is true?
    a. Drugs that kill with a small dose need further evaluation.
    b. Only drugs that are highly lethal need to include the lethal dose on their marketing materials.
    c. The effective dose is the dose that produces the desired effect.
    d. A dose can be called effective only if the amount of the test drug caused a defined effect in 75 percent of the animals.

ANSWER: c
RATIONALE: The effective dose is the dose that produces the desired effect. See Safety and Effectiveness Evaluation.
POINTS: 1
DIFFICULTY: Easy
REFERENCES: Safety and Effectiveness Evaluation
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
LEARNING OBJECTIVES: ROMI02.03 - Differentiate between effective dose and lethal dose.
KEYWORDS: Bloom's: Remember
DATE CREATED: 11/22/2019 8:38 AM
DATE MODIFIED: 11/22/2019 8:41 AM

11. What percentage of the animals receiving a drug must die in order for researchers to identify the lethal dose?
    a. 10 percent
    b. 25 percent
    c. 50 percent
    d. 75 percent

ANSWER: c
RATIONALE: The lethal dose is the dose of a test drug that kills 50 percent of the animals that receive it. See Safety and Effectiveness Evaluation.
POINTS: 1
DIFFICULTY: Easy
REFERENCES: Safety and Effectiveness Evaluation
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
LEARNING OBJECTIVES: ROMI02.03 - Differentiate between effective dose and lethal dose.

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KEYWORDS: Bloom's: Remember
DATE CREATED: 11/22/2019 8:41 AM
DATE MODIFIED: 11/22/2019 8:42 AM

12. What is the lethal dose of Valium® in mice?

a. 720 mg/kg given orally
b. 500 mg/kg given orally
c. 2,000 mg/kg given orally
d. 100 mg/kg given orally

ANSWER: a
RATIONALE: The lethal dose of Valium® given to mice orally is 720 mg/kg. See Safety and Effectiveness Evaluation.
POINTS: 1
DIFFICULTY: Easy
REFERENCES: Safety and Effectiveness Evaluation
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
LEARNING OBJECTIVES: ROMI02.03 - Differentiate between effective dose and lethal dose.
KEYWORDS: Bloom's: Remember
DATE CREATED: 11/22/2019 8:42 AM
DATE MODIFIED: 11/22/2019 8:44 AM

13. A dose can be called effective only if the amount of the test drug causes a defined effect in _____ of the animals that receive it.

a. 10 percent
b. 25 percent
c. 50 percent
d. 75 percent

ANSWER: c
RATIONALE: A dose can be called effective only if the amount of the test drug causes a defined effect in 50 percent of the animals that receive it. See Safety and Effectiveness Evaluation.
POINTS: 1
DIFFICULTY: Easy
REFERENCES: Safety and Effectiveness Evaluation
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
LEARNING OBJECTIVES: ROMI02.03 - Differentiate between effective dose and lethal dose.
KEYWORDS: Bloom's: Remember
DATE CREATED: 11/22/2019 8:44 AM
DATE MODIFIED: 11/22/2019 8:46 AM

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14. What value is determined by comparing the drug's LD_{50} and its ED_{50}?

a. Long-term toxicity
b. Systems-oriented screen
c. Chronic study
d. Therapeutic index

ANSWER: d
RATIONALE: The therapeutic index value is determined by comparing the drug's LD_{50} and its ED_{50}. See Safety and Effectiveness Evaluation
POINTS: 1
DIFFICULTY: Easy
REFERENCES: Safety and Effectiveness Evaluation
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
LEARNING OBJECTIVES: ROMI02.04 - Describe how margin of safety relates to the appearance of toxicity signs.
KEYWORDS: Bloom's: Remember
DATE CREATED: 11/22/2019 8:46 AM
DATE MODIFIED: 11/22/2019 8:48 AM

15. How long are tests conducted before they can be labeled non-carcinogenic?

a. Three months
b. Six months
c. Three years
d. Six years

ANSWER: b
RATIONALE: Researchers give large daily doses of a test drug to thousands of test animals for six months to see if cancerous tumors appear. After six months, each animal is inspected for tumors. See Safety and Effectiveness Evaluation.
POINTS: 1
DIFFICULTY: Easy
REFERENCES: Safety and Effectiveness Evaluation
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
LEARNING OBJECTIVES: ROMI02.06 - Describe how adverse drug effects are monitored.
KEYWORDS: Bloom's: Remember
DATE CREATED: 11/22/2019 8:48 AM
DATE MODIFIED: 11/22/2019 8:50 AM

16. What do systems-oriented screens test?

a. Toxicity

b. Physiological systems
c. Therapeutic indices
d. Margins of safety

ANSWER: b
RATIONALE: After the toxicity evaluation, researchers may conduct a systems-oriented screen, a test of the drug's effect on a particular physiological system. See Safety and Effectiveness Evaluation.
POINTS: 1
DIFFICULTY: Easy
REFERENCES: Safety and Effectiveness Evaluation
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
LEARNING OBJECTIVES: ROMI02.05 - Identify adverse effects monitored by the FDA.
KEYWORDS: Bloom's: Remember
DATE CREATED: 11/22/2019 8:50 AM
DATE MODIFIED: 11/22/2019 8:52 AM

17. If there is a small difference between an effective dose and a lethal dose then there is a _____.

a. narrow therapeutic index
b. broad therapeutic index
c. narrow shelf life
d. broad shelf life

ANSWER: a
RATIONALE: A narrow or lesser therapeutic index or margin of safety means that the patient must be monitored more closely because of the relatively small difference between the effective dose and the lethal dose. See Safety and Effectiveness Evaluation.
POINTS: 1
DIFFICULTY: Easy
REFERENCES: Safety and Effectiveness Evaluation
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
LEARNING OBJECTIVES: ROMI02.04 - Describe how margin of safety relates to the appearance of toxicity signs.
KEYWORDS: Bloom's: Remember
DATE CREATED: 11/22/2019 8:52 AM
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18. A greater therapeutic index is represented by a(n) _____ number.

a. equal
b. larger
c. smaller
d. zero

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ANSWER: b
RATIONALE: A greater therapeutic index is represented by a larger number. See Safety and Effectiveness Evaluation.
POINTS: 1
DIFFICULTY: Easy
REFERENCES: Safety and Effectiveness Evaluation
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
LEARNING OBJECTIVES: ROMI02.04 - Describe how margin of safety relates to the appearance of toxicity signs.
KEYWORDS: Bloom's: Remember
DATE CREATED: 11/22/2019 8:54 AM
DATE MODIFIED: 11/22/2019 8:55 AM

19. When calculating the therapeutic index, what is used as the measure of toxicity?

a. The effective dose
b. The lethal dose
c. The margin of safety
d. Toxic evaluation

ANSWER: b
RATIONALE: When calculating the therapeutic index, the lethal dose is used as the measure of toxicity. See Safety and Effectiveness Evaluation.
POINTS: 1
DIFFICULTY: Easy
REFERENCES: Safety and Effectiveness Evaluation
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
LEARNING OBJECTIVES: ROMI02.04 - Describe how margin of safety relates to the appearance of toxicity signs.
KEYWORDS: Bloom's: Remember
DATE CREATED: 11/22/2019 8:55 AM
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20. What is monitored during therapeutic drug therapy?

a. Temperature
b. Plasma levels
c. Blood pressure
d. Bone marrow

ANSWER: b
RATIONALE: The practice of monitoring drug levels in the plasma during therapy is called therapeutic drug monitoring. See Safety and Effectiveness Evaluation.
POINTS: 1

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DIFFICULTY: Easy
REFERENCES: Safety and Effectiveness Evaluation
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
LEARNING OBJECTIVES: ROMI02.04 - Describe how margin of safety relates to the appearance of toxicity signs.
KEYWORDS: Bloom's: Remember
DATE CREATED: 11/22/2019 8:57 AM
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21. If the LD_{50} and ED_{50} values are known for a given drug, how can you determine the therapeutic index?

a. By subtracting the LD_{50} value by the ED_{50} value
b. By adding the LD_{50} value by the ED_{50} value
c. By multiplying the LD_{50} value by the ED_{50} value
d. By dividing the LD_{50} value by the ED_{50} value

ANSWER: d
RATIONALE: If the LD_{50} and ED_{50} values are known for a given drug, its therapeutic index is determined by dividing the LD_{50} value by the ED_{50} value. See Safety and Effectiveness Evaluation.
POINTS: 1
DIFFICULTY: Easy
REFERENCES: Safety and Effectiveness Evaluation
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
LEARNING OBJECTIVES: ROMI02.04 - Describe how margin of safety relates to the appearance of toxicity signs.
KEYWORDS: Bloom's: Remember
DATE CREATED: 11/22/2019 8:59 AM
DATE MODIFIED: 11/22/2019 9:01 AM

22. When researchers are testing for fetal defects, they are testing for which adverse effect?

a. Carcinogenicity
b. Teratogenicity
c. Reproductivity
d. Toxicity

ANSWER: b
RATIONALE: The FDA requires that all drugs be tested to see if they cause fetal defects in animals, called teratogenicity tests. See Safety and Effectiveness Evaluation.
POINTS: 1
DIFFICULTY: Easy
REFERENCES: Safety and Effectiveness Evaluation

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QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
LEARNING OBJECTIVES: ROMI02.05 - Identify adverse effects monitored by the FDA.
KEYWORDS: Bloom's: Remember
DATE CREATED: 11/22/2019 9:01 AM
DATE MODIFIED: 11/22/2019 9:02 AM

23. After a drug is approved, is any further testing done?
    a. No, once approved all testing is stopped.
    b. No, because further testing may reveal adverse effects.
    c. Yes, long-term toxicity tests continue for up to two years.
    d. Yes, if the company so decides to continue testing.

ANSWER: c
RATIONALE: Researchers conduct long-term toxicity tests, also called chronic studies, that run anywhere from three months to two years to prevent disastrous consequences of a drug therapy. See Safety and Effectiveness Evaluation.
POINTS: 1
DIFFICULTY: Easy
REFERENCES: Safety and Effectiveness Evaluation
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
LEARNING OBJECTIVES: ROMI02.05 - Identify adverse effects monitored by the FDA.
KEYWORDS: Bloom's: Remember
DATE CREATED: 11/22/2019 9:02 AM
DATE MODIFIED: 11/22/2019 9:04 AM

24. Who can report an adverse reaction to the FDA?
    a. Veterinarians
    b. Animal owners
    c. Manufacturers
    d. All of the choices are correct.

ANSWER: d
RATIONALE: The manufacturer is required to report adverse reactions to the FDA; however, veterinarians and animal owners can also file a report directly with the FDA Adverse Event Reporting System (FAERS) by following the instructions on the FDA web site. See Safety and Effectiveness Evaluation.
POINTS: 1
DIFFICULTY: Easy
REFERENCES: Safety and Effectiveness Evaluation
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False

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LEARNING OBJECTIVES: ROMI02.06 - Describe how adverse drug effects are monitored.
KEYWORDS: Bloom's: Remember
DATE CREATED: 11/22/2019 9:04 AM
DATE MODIFIED: 11/22/2019 9:06 AM

25. When will the FDA approve a drug for general use even if it can cause birth defects?
    a. If the risk to the fetus is so small in number that it is unlikely to occur
    b. If the benefits of the drug are far greater than the risk to the fetus
    c. If the manufacturer can demonstrate that the adverse effects no longer exist in certain breeds
    d. If the therapeutic index has narrowed to such a number that the FDA is now comfortable with the risk

ANSWER: b
RATIONALE: Because these defects could be produced in any pregnant animals taking the drug, the FDA will typically not approve it for general use unless the benefits of the drug are far greater than the risk they pose to the fetus. See Safety and Effectiveness Evaluation.
POINTS: 1
DIFFICULTY: Easy
REFERENCES: Safety and Effectiveness Evaluation
QUESTION TYPE: Multiple Choice
HAS VARIABLES: False
LEARNING OBJECTIVES: ROMI02.06 - Describe how adverse drug effects are monitored.
KEYWORDS: Bloom's: Remember
DATE CREATED: 11/22/2019 9:06 AM
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