Adams and Urban, *Pharmacology: Connections to Nursing Practice*, 2e Test Bank

Chapter 2

Question 1
Type: MCSA

In early America, there were many patent medicines. Problems with patent medicines led to legislation of drugs. Which one of the suggested choices was the greatest problem with patent medicines?

1. They were only distributed in elixir formulation.

2. They had dangerous or addictive substances.

3. They smelled like medicine.

4. They could only be made out of natural products.

Correct Answer: 2

Rationale 1: They could be distributed in many forms, such as tablets and creams, not just elixirs.

Rationale 2: Many did contain dangerous or addictive substances such as morphine or cocaine.

Rationale 3: Some did have a medicine smell, but this was not dangerous.

Rationale 4: They could be made out of many products, not just natural ones.

Global Rationale:

Cognitive Level: Remembering
Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-1

Question 2
Type: MCMA

During the rise of patent medicines in early America in the 1800s, there were few attempts to regulate drugs. Which statements accurately depict this situation?

Note: Credit will be given only if all correct choices and no incorrect choices are selected.

Standard Text: Select all that apply.

1. Patent medicines contained a brand name that clearly identified the product.

2. Patent medicines claimed to cure just about any disease or condition.

3. Patent medicines were often harmless and ineffective.

4. Many patent medicines contained addictive substances.

5. Patent medicines could not make false therapeutic claims.

Correct Answer: 1,2,3,4

Rationale 1: Patent medicine did contain the brand name clearly identifying the product.

Rationale 2: Patent medicine claimed to cure everything from consumption to "all forms of weakness."

Rationale 3: Many patent medicines contained coloring and flavoring and were both harmless and ineffective.

Rationale 4: Some elixers contained up to 50% morphine. In the late 1800s, Coca-Cola contained about 9 mg of cocaine per serving.

Rationale 5: It was not until the Sherley Amendment was passed in 1912 that false therapeutic claims were prohibited.

Global Rationale:

Cognitive Level: Remembering
Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-1

Question 3
Type: MCSA

The student nurse taking a pharmacology class is studying the Food, Drug, and Cosmetic Act of 1938. What is important for the student to remember?

1. It prevented the sale of drugs that had not been tested before marketing.

2. It gave the government the power to change labeling content of medications.

3. It helped to standardize the quality of prepared food, drugs, and cosmetics.

4. It prohibited the sale of drugs labeled with false therapeutic claims to defraud the public.

Correct Answer: 1

Rationale 1: It did prevent sale of drugs that had not been tested before marketing.

Rationale 2: It did not give the government power over labeling contents; the Pure Food and Drug Act did.

Rationale 3: It did not standardize quality of food, drugs, or cosmetics.

Rationale 4: It did not prohibit sale of drugs labeled with false therapeutic claims to defraud the pubic; this was the Sherley Amendment.

Global Rationale:

Cognitive Level: Applying
Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-2

Question 4
Type: MCSA

A client is talking to the nurse and is expressing doubt about whether to take a drug that is advertised on television. The client does not believe that commercials for drugs tell the truth. The nurse's response is based on what understanding?

1. Advertisements are not legally binding and can be misleading.

2. All drugs must be advertised in media to inform the public.

3. Manufacturers have some ability to change things when advertising drugs.

4. False claims of a drug's therapeutic effect are prohibited by law.

Correct Answer: 4

Rationale 1: It is illegal to advertise false claims; advertisements are legally binding.

Rationale 2: Drugs do not have to be advertised in the media.

Rationale 3: Manufacturers may not change the truth when advertising drugs.

Rationale 4: The Sherley Amendment of 1912 prohibits sale of drugs labeled with false therapeutic claims.

Global Rationale:

Cognitive Level: Applying
Client Need: Physiological Integrity

Client Need Sub: Pharmacological and Parenteral Therapies
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-2

Question 5
Type: MCMA

The Pure Food and Drug Act (PFDA) of 1906 was significant in that it gave the government the power to prohibit drug labels from claiming false therapeutic benefits. However, there were still several weaknesses in the legislature of this act. Which statements most accurately describe these weaknesses?

Note: Credit will be given only if all correct choices and no incorrect choices are selected.

Standard Text: Select all that apply.

1. This law did not require drug manufacturers to prove that the drug was effective in its claims.

2. This law did not prevent drugs from being marketed for any disease.

3. This law required all drug labels to accurately describe the contents.

4. This law required adequate testing for safety prior to marketing.

5. This law did not encourage the development of drugs for rare or unusual disorders.

Correct Answer: 1,2

Rationale 1: The fact that manufacturers did not have to prove efficacy was a tremendous weakness in the regulation of drugs in the early 20th century.

Rationale 2: The PFDA of 1906 did not address false therapeutic claims.

Rationale 3: Requiring drug labels to identify their contents is not a weakness of the PFDA.

Rationale 4: The PFDA did not require testing for safety prior to marketing. It was not until Congress passed the Food, Drug, and Cosmetic Act that drugs had to be tested for safety prior to marketing.

Rationale 5: The act that encouraged the research and development of drugs for rare or unusual disorders is called the Orphan Act.

Global Rationale:

Cognitive Level: Remembering
Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies
Nursing/Integrated Concepts: Nursing Process: Implementation

Learning Outcome: 2-2

Question 6
Type: MCSA

One of the first standards used by pharmacists for preparation and potency of drugs was a formulary. What did early formularies contain?

1. Names of patent medicines and natural drugs

2. Lists of pharmaceutical products and drug recipes

3. Lists of various drugs' strengths based on individual pharmacies

4. Lists of various drugs' potency based on geographic region

Correct Answer: 2

Rationale 1: Early formularies did not contain the names of patent medicines and natural drugs.

Rationale 2: Early formularies did contain a list of pharmaceutical products and drug recipes.

Rationale 3: Formularies did not list drugs based on the individual pharmacies.

Rationale 4: Formularies did not list drugs by their geographical region.

Global Rationale:

Cognitive Level: Remembering
Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-3

Question 7
Type: MCMA

In the early 1800s, it became clear that the standardization of drug purity and strength was necessary. Which reasons reflected this need?

Note: Credit will be given only if all correct choices and no incorrect choices are selected.

Standard Text: Select all that apply.

1. Strength and purity of products varied from region to region and batch to batch.

2. Strength and purity of products depended on the pharmacist's experience.

3. Strength and purity of products would vary in size, taste, and nutritional value.

4. Strength and purity were mostly guaranteed if products were produced locally, which caused a hardship for those outside the region.

5. Strength and purity could be trusted when the product had gone through extensive local testing.

Correct Answer: 1,2,3

Rationale 1: The strength and purity of the products varied considerably because they were dependent on the experience of the pharmacist and the quality of the local ingredients, which could vary from region to region and batch to batch.

Rationale 2: The strength and purity of the products varied considerably because they were dependent on the experience of the pharmacist and the quality of the local ingredients, which could vary from region to region and batch to batch.

Rationale 3: The strength and purity of the products varied considerably because they were dependent on the experience of the pharmacist and the quality of the local ingredients, which could vary from region to region and batch to batch.

Rationale 4: Strength and purity could not be guaranteed, even if produced locally. Causing a hardship on those outside the region had nothing to do with determining that standardization was needed.

Rationale 5: Extensive testing prior to marketing did not occur until the early 1930s.

Global Rationale:

Cognitive Level: Remembering
Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-3

Question 8
Type: MCSA

A pharmaceutical representative comes to the primary care office and states that his company is marketing a new drug that does not need approval by the Food and Drug Administration (FDA). What is the best response of the nurse?

1. "Is this a drug in clinical trials? Those are the only drugs that don't have to have FDA approval."

2. "Is this an over-the-counter drug? Over-the-counter drugs do not need FDA approval."

3. "Your company must be involved in academic research if the drug doesn't need FDA approval."

4. "Any pharmaceutical company must have FDA approval before marketing a drug."

Correct Answer: 4

Rationale 1: Drugs in clinical trials must have FDA approval to start and continue clinical trials.

Rationale 2: Over-the-counter drugs must have FDA approval before being marketed.

Rationale 3: Drugs involved in academic research must have FDA approval.

Rationale 4: All drugs marketed by pharmaceutical companies must have FDA approval.

Global Rationale:

Cognitive Level: Applying
Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-4

Question 9
Type: MCSA

Nursing students are studying which drug types must have Food and Drug Administration (FDA) approval before being marketed. The students know that which drugs must have approval from the FDA before being marketed?

1. Biologics

2. Food supplements

3. Herbal preparations

4. Dietary supplements

Correct Answer: 1

Rationale 1: Biologics must have FDA approval before being marketed.

Rationale 2: Food supplements do not require FDA approval.

Rationale 3: Herbal preparations do not require FDA approval.

Rationale 4: Dietary supplements do not require FDA approval.

Global Rationale:

Cognitive Level: Understanding
Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-4

Question 10
Type: MCMA

Which statements regarding the role of the U.S. Food and Drug Administration (FDA) are true?

Note: Credit will be given only if all correct choices and no incorrect choices are selected.

Standard Text: Select all that apply.

1. The FDA is responsible for ensuring the security of human drugs.

2. The FDA publishes a summary of the standards of drug purity and strength.

3. The FDA ensures the availability of effective drugs.

4. The FDA takes action against any supplement that is deemed to be unsafe.

5. The FDA facilitates the availability of safe drugs.

Correct Answer: 1,3,4,5

Rationale 1: The FDA mission is to protect public health by ensuring the safety, efficacy and security of human and veterinary drugs, biologic products, medical devises, the nation's food supply, cosmetics, and products that emit radiation.

Rationale 2: It is the role of the U.S. Pharmacopeia (USP) to publish a summary of drug standards (purity and strength).

Rationale 3: Ensuring the availability of effective drugs is one of the FDA's roles.

Rationale 4: It is the FDA's role to take action against any supplement that is deemed to be unsafe.

Rationale 5: It is the role of the FDA to facilitate the availability of safe drugs.

Global Rationale:

Cognitive Level: Remembering
Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies

Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-4

Question 11
Type: MCSA

The nurse explains to the client that during the Food and Drug Administration (FDA) drug approval process, clinical investigators from many different medical specialties address concerns. What concerns are addressed?

1. Whether a New Drug Application (NDA) must be filed

2. The marketability of the drug

3. What the cost of the drug should be

4. Whether or not the drug is safe

Correct Answer: 4

Rationale 1: The pharmaceutical company files the NDA.

Rationale 2: The clinical investigators do not determine marketability of the drug.

Rationale 3: Clinical investigators do not determine the cost of the drug.

Rationale 4: Safety is determined by the FDA during the Investigational New Drug Application process.

Global Rationale:

Cognitive Level: Remembering
Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-5

Question 12
Type: MCSA

The client receiving a newly released medication is experiencing adverse effects. Why does the nurse report these adverse effects as part of the postmarketing surveillance stage of the drug approval process?

1. The clinical trials are continuing to collect new data.

2. Individual client response is compared with the clinical trial data.

3. The efficacy of the drug is determined for new drugs.

4. Harmful effects in the larger population continue to be monitored.

Correct Answer: 4

Rationale 1: The clinical trials end before the drug is released for use by the general public.

Rationale 2: The client's response is not compared with previous clinical trials.

Rationale 3: The efficacy for the drug is not evaluated via the adverse effects.

Rationale 4: Some harmful effects are subtle, take longer to appear, and are not identified until the drug is prescribed to a large number of people; thus, postmarketing surveillance for harmful effects must be reported.

Global Rationale:

Cognitive Level: Applying
Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-5

Question 13
Type: MCMA

Which statements regarding the preclinical research stage of drug development are true?

Note: Credit will be given only if all correct choices and no incorrect choices are selected.

Standard Text: Select all that apply.

1. Most drugs do not proceed past the preclinical stage because they are found to be too toxic or just ineffective.

2. At the end of the preclinical research stage, client variability is determined and potential drug-to-drug interactions are examined.

3. The preclinical stage of research involves extensive testing on animals in the laboratory to determine if the drug will cause harm to humans.

4. Preclinical research results are always inconclusive.

5. The Food and Drug Administration (FDA) is responsible for extensive testing for safety before the pharmaceutical company can begin the preclinical research stage of development.

Correct Answer: 1,3,4

Rationale 1: Most drugs do not proceed past the preclinical research stage of development because they are found to be either too toxic or just ineffective.

Rationale 2: Client variability and potential drug-to-drug interactions are examined in Phase 3 of the clinical investigation process after Food and Drug Administration (FDA) approval.

Rationale 3: The preclinical stage involves extensive testing on human, microbial cells, and animals to determine drug action and to predict whether the drug will cause harm to humans.

Rationale 4: Because lab tests cannot accurately predict human response to a drug, these results are always inconclusive.

Rationale 5: This extensive testing is done by the pharmaceutical company in the preclinical research stage of drug development, not the FDA.

Global Rationale:

Cognitive Level: Remembering
Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-5

Question 14
Type: MCSA

Clients enrolled in a clinical drug trial are told that they might receive a placebo drug as part of a control group. A client asks the nurse what a placebo is. What is the nurse's best response?

1. “A placebo is a substance that has no therapeutic effect.”

2. "A placebo is a similar drug that is safe."

3. "A placebo is a drug that has been tested before."

4. "A placebo is an over-the-counter drug."

Correct Answer: 1

Rationale 1: A placebo is an inert substance that has no therapeutic effect used as a control.

Rationale 2: A placebo is not a similar drug

Rationale 3: A placebo is generally not another drug.

Rationale 4: A placebo is not an over-the-counter drug

Global Rationale:

Cognitive Level: Remembering

Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-6

Question 15
Type: MCSA

The nursing student is studying how priority drugs receive accelerated approval by the Food and Drug Administration (FDA) as part of the FDA modernization. The student knows that priority drugs are used to treat which conditions?

1. Diseases that previously were treated with older and less popular drugs

2. Diseases that affect only a small percentage of the population

3. Diseases for which the community raises money for treatment

4. Serious and life-threatening conditions that lack effective treatments

Correct Answer: 4

Rationale 1: The process does not cover only diseases that were covered with older drugs, but also diseases that are serious and lack effective treatment.

Rationale 2: There are serious diseases that affect only a small percentage of the population, but this is not a criterion for the accelerated process.

Rationale 3: Although the community might raise money for serious and life-threatening conditions, that is not a criterion for accelerated FDA approval.

Rationale 4: The accelerated approval process is for drugs for serious and life-threatening conditions

Global Rationale:

Cognitive Level: Applying
Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-7

Question 16
Type: MCSA

The nurse is teaching a class about over-the-counter (OTC) medications at a senior citizen center. The nurse knows that the teaching was effective when the center members make which statement?

1. "Over-the-counter medications are safe, as long as we don't take them at the same time as our prescription medications."

2. "Over-the-counter medications are safe; otherwise, they would require a prescription."

3. "We should not take any over-the-counter medications without first calling our primary health care provider because these medications can interact with other prescriptions or products."

4. "We must read all the label directions before taking any over-the-counter medications."

Correct Answer: 3

Rationale 1: Some OTC medications can be taken with prescription medications; others cannot.

Rationale 2: Although they have a high margin of safety, OTC medications are not without risks.

Rationale 3: Elderly clients often take multiple medications and should consult with their health care provider before taking any over-the-counter medication or supplement to ensure there are no risks for drug interactions.

Rationale 4: It is important for clients to read all directions on the label, but this will not protect them if there is a contraindication with another medication they are taking; therefore, they must consult their primary health care provider before taking any OTC medications.

Global Rationale:

Cognitive Level: Applying
Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies
Nursing/Integrated Concepts: Nursing Process: Evaluation
Learning Outcome: 2-8

Question 17
Type: MCSA

The client was taking a prescription medication that is now available over the counter. The client asks the nurse, "Why do some medications become available over the counter and other medications remain prescription drugs?" The nurse's answer is:

1. "Drugs with the least amount of side effects can become over-the-counter."

2. "Drugs that have a high safety margin may be reclassified to over the counter."

3. "The longer the drug is on the market, the better its chance of going over the counter."

4. "If the pharmaceutical company pays the FDA a large amount of money, they can have their drug reclassified."

Correct Answer: 2

Rationale 1: The number of side effects does not determine whether a drug is to be considered for over-the-counter (OTC) classification.

Rationale 2: Drugs that have a high safety margin may be reclassified as OTC drugs.

Rationale 3: The amount of time a drug is on the market does not influence the ability to change to OTC. Many drugs have been available for over 100 years and remain prescription.

Rationale 4: The FDA does not select drugs for OTC status based on fees paid by drug companies.

Global Rationale:

Cognitive Level: Applying
Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-8

Question 18
Type: MCMA

A client says to the admitting nurse, "Why do you need to know the names of all the over-the-counter supplements I take? They aren't drugs." Which of the nurse's responses are appropriate?

Note: Credit will be given only if all correct choices and no incorrect choices are selected.

Standard Text: Select all that apply.

1. "The admitting physician needs to know everything you are taking."

2. "You're right. I'm not sure why the admitting paperwork asks for this information. Would you mind listing them anyway?"

3. "The law requires us to keep a list of over-the-counter drugs and supplements that you are taking."

4. "It is true that supplements are not considered drugs; however, some of these products can cause adverse effects with prescribed drugs."

5. "We need to know if you are having an allergic reaction to one of them."

Correct Answer: 1,4

Rationale 1: The health care providers involved in this client's care will need to know everything she is taking—both prescription and over-the-counter (OTC).

Rationale 2: While it is true that supplements are not considered drugs, there is a specific reason why the health care team needs to know this information, which is the reason for the requested list on the paperwork. The nurse's answer did not address the client's question appropriately.

Rationale 3: No law requires hospitals to keep records of OTC drugs and supplements that clients take. This information is needed, however, for other reasons.

Rationale 4: Supplements are not subject to the same regulatory process as drugs, and some of these products can cause adverse effects and interact with medications.

Rationale 5: It is possible that this client could be having an allergic reaction, but there is not enough information to determine this, and this is not the main reason why the health care team needs to know what OTC medications she is taking.

Global Rationale:

Cognitive Level: Applying
Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-8

Question 19
Type: MCSA

The client says to the nurse, "I wonder if I am considered a drug addict. I went to pick up my medication from the drug store and the pharmacist told me that the drug was a controlled substance." What is the nurse's best response?

1. "If you continue on this medication for a long time, you will become addicted to it."

2. "You are not an addict, but the Drug Enforcement Agency (DEA) will be watching your prescription drug habits now."

3. "Any drug that has a potential for abuse is considered a controlled substance and is restricted. This does not mean the pharmacist will think you are an addict."

4. "Do you think that you are addicted to your medication?"

Correct Answer: 3

Rationale 1: Clients can be on controlled substances for various lengths of time without becoming addicted.

Rationale 2: The DEA does not monitor the prescription drug habits of every client who receives a controlled substance.

Rationale 3: The pharmacist recognizes all drugs with the potential for abuse are considered controlled substances and carry restrictions but most likely will not think the client is a drug addict.

Rationale 4: Asking the client if he thinks he is addicted does not answer his question about controlled substances.

Global Rationale:

Cognitive Level: Applying
Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-9

Question 20
Type: MCSA

The nurse is working in a cancer treatment center. The client has terminal cancer and has received a prescription for morphine (MS Contin), a schedule II drug for pain control. The nurse is teaching this client about the medication, and determines that the teaching is successful when the client makes what statement?

1. "I should call the office three days before I need a refill called in to the pharmacy."

2. "I will need to see the provider each time for my refill."

3. "This is an addictive drug, so I should try not to take it."

4. "After the first prescription, my doctor will be able to call in my prescription."

Correct Answer: 2

Rationale 1: Schedule II drugs cannot not have refills called into the pharmacy.

Rationale 2: The client will need to see the provider each time a refill is needed.

Rationale 3: The client should take the drug as it is needed and directed. The client might not become addicted to the drug.

Rationale 4: Schedule II medications cannot be called into the pharmacy.

Global Rationale:

Cognitive Level: Applying
Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies
Nursing/Integrated Concepts: Nursing Process: Implementation

Learning Outcome: 2-9

Question 21
Type: MCSA

A client plans to obtain his prescription and over-the-counter medications and supplements from Canada. What similarity does the nurse recognize that the drug approval processes in Canada and the United States share?

1. Herbal products are not monitored in Canada.

2. Prescription medications are often sold over the counter in Canada.

3. Natural products do not have to be monitored.

4. Dietary supplements have to be monitored.

Correct Answer: 4

Rationale 1: Herbal products must be monitored in both countries.

Rationale 2: Prescription medications are not sold over the counter in either country.

Rationale 3: Natural products must be monitored in both countries.

Rationale 4: Dietary supplements do have to be monitored in both countries.

Global Rationale:

Cognitive Level: Applying
Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies
Nursing/Integrated Concepts: Nursing Process: Assessment
Learning Outcome: 2-10

Question 22
Type: MCMA

The nurse, explaining to a client the importance a placebo plays in drug research, bases this explanation on which information?

Note: Credit will be given only if al correct choices and no incorrect choices are selected.

Standard Text: Select all that apply.

1. The research drug must be compared to an inert substance to determine effectiveness.

2. The placebo will be given to a control group, and those results will be compared to the group taking the research drug.

3. Neither group during the trails will know if they have the placebo drug or the research drug.

4. The research drug will be considered for a New Drug Application (NDA) if it is found to be effective and safe when compared to the placebo drug.

5. Before the clinical trials, the research drug will be tested on select clients against another standard drug used for the same condition.

Correct Answer: 1,2,3,4

Rationale 1: The primary focus of a clinical trial is to provide information regarding the effectiveness of the research drug. The effectiveness of the research drug will be compared to an inert substance taken by a nontreatment group, called the *control group*.

Rationale 2: The primary focus of a clinical trial is to provide information regarding the effectiveness of the research drug. The effectiveness of the research drug will be compared to an inert substance taken by a nontreatment group, called the *control group*.

Rationale 3: Clients may have a perceived or actual improvement in a medical condition if they know they are taking the research drug. Clients may also feel there is no improvement if they know they are taking a drug that has inert properties.

Rationale 4: If the research drug continues to show that it is effective and safe, an NDA will be submitted to the Federal Drug Administration (FDA).

Rationale 5: In some cases, the research drug may be compared to a standard drug used for the same condition, but only during clinical trials. Preclinical research does not include testing on humans.

Global Rationale:

Cognitive Level: Applying
Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-6

Question 23
Type: MCMA

A nurse who has accepted a traveling assignment to Canada is reviewing the similarities between the American and Canadian drug approval processes. What do these similarities include?

Note: Credit will be given only if all correct choices and no incorrect choices are selected.

Standard Text: Select all that apply.

1. The United States and Canada have strict guidelines for drug approval.

2. Drug testing and risk assessment are important priorities in both the United States and in Canada.

3. In both the United States and Canada, drug testing relies extensively on government resources.

4. Both the United States and Canada have agencies responsible for ensuring the safety of health products and foods.

5. Manufacturers in both the United States and Canada must present sufficient scientific evidence of a product's safety, efficacy, and quality before marketing.

Correct Answer: 1,2,4,5

Rationale 1: Both the United States and Canada have strict guidelines for drug approval.

Rationale 2: In both the United States and Canada, drug testing and risk assessment are priorities.

Rationale 3: In the United States, private and government resources are used; in Canada, only government resources are used.

Rationale 4: The Food and Drug Administration of the United States and the Health Products and Food Branch of Health Canada are responsible for public safety.

Rationale 5: In both countries, manufactures must provide scientific evidence of a product's safety, efficacy, and quality prior to marketing.

Global Rationale:

Cognitive Level: Understanding
Client Need: Physiological Integrity
Client Need Sub: Pharmacological and Parenteral Therapies
Nursing/Integrated Concepts: Nursing Process: Implementation
Learning Outcome: 2-10