

Chapter 3: Drug Regulation, Development, Names, and Information Test Bank

MULTIPLE CHOICE

1. A nurse educator is conducting a continuing education class on pharmacology. To evaluate the learning of the nurses in the class, the nurse educator asks, "Which drug name is a generic drug name?" Which is the correct response?
 - a. Acetaminophen
 - b. Tylenol
 - c. Cipro
 - d. Motrin

ANS: A

Acetaminophen is the generic name. Tylenol, Cipro, and Motrin are all trade names.

DIF: Cognitive Level: Comprehension REF: Table 3-3: The Three Types of Drug Names

TOP: Nursing Process: Diagnosis

MSC: NCLEX Client Needs Category: Physiologic Integrity: Pharmacologic and Parenteral Therapies

2. The FDA Amendments Act (FDAAA) was passed in 2007 to address which aspect of drug safety?
 - a. Allowing pharmaceutical companies to identify off-label uses of medications approved for other uses
 - b. Evaluating drug safety information that emerges after a drug has been approved and is in use
 - c. Expediting the approval process of the U.S. Food and Drug Administration (FDA) so that needed drugs can get to market more quickly
 - d. Requiring manufacturers to notify patients before removing a drug from the market

ANS: B

The FDAAA was passed to enable the Food and Drug Administration to continue oversight of a drug after granting it approval so that changes in labeling could be made as necessary and postmarketing risks could be tracked and identified. A provision of the FDA Modernization Act (FDAMA), passed in 1997, allows drug companies to promote their products for off-label uses as long as they promise to conduct studies to support their claims. Regulations to permit accelerated approval of drugs for life-threatening diseases were adopted in 1992 by the FDA. The requirement that drug companies notify patients 6 months before removing a drug from the market is a provision of the FDAMA.

DIF: Cognitive Level: Comprehension REF: Landmark Drug Legislation

TOP: Nursing Process: Evaluation

MSC: NCLEX Client Needs Category: Physiologic Integrity: Pharmacologic and Parenteral Therapies

3. A nursing student asks a nurse about pharmaceutical research and wants to know the purpose of randomization in drug trials. The nurse explains that randomization is used to:
 - a. ensure that differences in outcomes are the result of treatment and not differences in subjects.
 - b. compare the outcome caused by the treatment to the outcome caused by no treatment.

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