uBEATS Teacher's Guide:

Introduction to FDA Approval

(Grades 11-12)

This teacher guide is a supplementary text to support the use of the uBEATS "Introduction to FDA Approval" pharmacology module for grades 11-12.

To help students develop the knowledge necessary for an incredible future in health care, we created UNMC Building Excellence in Academics Through STEM (uBEATS), an online health science resource for Nebraska students.

UNMC uBEATS modules are short (15 minutes or less), interactive online health science modules to supplement curriculum taught in grades 6 – 12. These do not replace curriculum, but are a supplement for teachers and students incorporating evidence based information and UNMC expert guided material. Each module is chunked into sections with formative and summative assessments with immediate feedback provided.

Tips on how to utilize uBEATS modules:

- Internet access is required to view uBEATS modules.
- For those who have access to one-to-one technology, modules can be used in or outside of the classroom as a topic introduction, extension, or review.
- For classrooms without individual student devices modules can be used in whole group instruction. Formative assessment questions can use the teacher's preferred call and response method and summative assessment questions can be displayed on the board and answered individually by students or printed and distributed to students after viewing the module.

Objectives

- Describe the role of the FDA in the drug approval process.
- Compare how various types of drugs are regulated: over-the-counter (OTC), prescription, investigational, herbals, supplements.
- Distinguish between generic and brand-name drugs.

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Introduction

Have you ever wondered what being "FDA Approved" really means? The Food and Drug Administration (FDA) is the authority behind ensuring the nation's public health is well-protected and maintained. They do this through the comprehensive regulation of the United States' food supply, drugs, medical devices, vaccines, and even cosmetics! In a sense, the FDA is the main reason why we can live our daily lives without having to worry about what we are putting into our bodies. If it weren't for the FDA constantly checking the quality and safety of our consumed products, we might not live in the same world that we do today!

When we go to the pharmacy for a nasty cold or have our healthcare providers prescribe us medicines for us to consume, there's a lot that goes on behind the scenes that we don't always see. It is much more complex than just walking up to the pharmacy and picking up your medications! America is known for having one of the most secure and advanced systems for pharmaceuticals in the entire world. This process starts with the Center for Drug Evaluation and Research (CDER). This center is most commonly known for its role in the evaluation of new drugs before they hit the consumer shelves. They prevent drugs that are not quite ready for consumer use before they ever reach the hands of a customer. They also issue health care providers and patients materials on the best ways to use these pharmaceutical goods. The CDER super-team is composed of some of the most diverse fields of science! Professionals like physicians, chemists, pharmacologists, and other scientists are all hard at work ensuring the data and labeling from the drug company is accurate and factual. These professionals ensure that the American people only get the safest and most effective drugs for use.

Prior Knowledge

Before beginning this module, the student should understand the Next Generation Science Standards (NGSS) featuring Three-Dimensional Learning.

Core Idea PS1.B. Chemical Reactions A Framework for K-12 Science Education

- Substances react chemically in characteristic ways. In a chemical process, the atoms that make up the original substances are regrouped into different molecules, and these new substances have different properties from those of the reactants. The total number of each type of atom is conserved, and thus the mass does not change. Some chemical reactions release energy, others store energy.

Science and Engineering Practices NGSS

- Constructing explanations and designing solutions

Crosscutting Concepts NGSS

- Structure and function

Key Terms/Vocabulary

Food and Drug Administration (FDA), pharmaceuticals, prescription drugs, over-the-counter (OTC) drugs, OTC Monograph, investigational new drugs (IND), Investigator IND, Emergency Use IND, Treatment IND, herbals, supplements, vitamins, minerals, enzymes, generic drugs, brand-name drugs, Center for Drug Evaluation and Research (CDER), animal testing, toxicity, efficacy, side effects, Investigational New Drug application (IND), Phase 1 of Clinical Trials, Phase 2 of Clinical Trials, placebo, Phase 3 of Clinical Trials, long-term effects, New Drug Application, Phase 4 of Clinical Trials.

Science Standards

Nebraska Science Standards

SC.HSP.3 Structure and Properties of Matter

- SC.HSP.3.3.D Evaluate a solution to a complex, real-world problem based on prioritized criteria and tradeoffs that account for a range of constraints, including cost, safety, reliability, and aesthetics, as well as possible social, cultural, and environmental impacts.

Extensions of the lesson

- To help students become more familiar with the Key Terms of this module, the teacher can use the vocabulary list for a classroom Word Wall, or integrate the vocabulary into classroom word games during review sessions.
- To help the students see personal relevance, suggest that they examine the data sheet provided by the pharmacy for a prescription medication used in the home.
- As student misconceptions become apparent, the teacher may need to reinforce these important concepts:
    - The U.S. Food and Drug Administration (FDA) has a rigorous process for ensuring the safety and effectiveness of new drugs created by research. This approval process takes at least 10 years.
    - Before clinical trials can be conducted with humans, preclinical trials must be done with live animals to detect potential safety hazards of the new drug.
    - Phase 1 clinical trials are done with fewer than 100 human volunteers in order to determine safe dosing ranges and to identify common side effects. This phase is completed with only healthy individuals. It does not test to see how effective the medicine might be for a particular condition.
    - Phase 2 clinical trials test 100-300 volunteers who actually have the targeted condition. Some of the test subjects are given the new medicine and other test subjects are given a placebo. This phase is designed to find out how effective the drug is at various doses and methods of delivery.

- Phase 3 clinical trials take the longest time and include the greatest number of volunteers (more than 1,000) in order to confirm that the drug is safe and effective for large cohorts of test subjects having the targeted condition.
- After these three phases of clinical trials successfully demonstrate that the drug is safe and effective, the New Drug Application can be submitted to the FDA for independent review. The drug can be manufactured and sold only if the FDA approves this application.
- Even if approval is granted, the FDA may require additional study in Phase 4 clinical trials to assess long-term risks and benefits, and to monitor the drug's effects within special populations.
- OTC drugs can be purchased at other stores besides pharmacies, but are still regulated by the Office of Nonprescription Drugs within the FDA's Center for Drug Evaluation and Research (CDER).
- Prescription drugs can be prescribed by physicians, physicians assistants, nurse practitioners, and dentists.
- Most herbals are not regulated by the FDA, but some herbals are supplements. Supplements are regulated by the FDA, but not as drugs or food. Herbal supplements are regulated as "dietary supplements."
- A generic drug may be priced lower than the equivalent brand-name drug, but it is required to have the same molecular formula, safety, strength, and route of administration as its brand-name counterpart. This is monitored by the FDA in its Generic Drug Program.

Enrichment

- For information about career opportunities, see UNMC's Careers in Healthcare.
- Students should be watchful in current events for recent stories about the Food and Drug Administration (FDA).
- To learn more about how the FDA regulates herbal supplements, see Dietary Supplements.
- To study differences between generic and brand-name medications, see MedicineNet.
- To make connections in your community, contact local universities, medical centers, drug manufacturers, and pharmacists.