



CASE STUDY

→ Drug Approval—Bringing a New Drug to the Market

A SMALL PHARMACEUTICAL COMPANY REVIEWS THE PATH LEADING TO FDA APPROVAL TO MARKET A NEW DRUG IN THE UNITED STATES

THE FDA CDER DRUG APPROVAL CASE STUDY IS A NEW LEARNING TOOL DESIGNED TO ADVANCE KNOWLEDGE, INSIGHT AND UNDERSTANDING OF FDA'S DRUG REGULATORY PROCESSES.

distributed free-of-charge. It can be found at the FDA website [www.fda.gov/Training/ForHealthProfessionals/ucm464124.htm].

Who is it for?

- Students and health professionals interested in drug development (including medical and pharmacy students)
- Pharmaceutical and clinical innovators
- Small business staff
- Patients and patient advocacy groups

What does it cover?

The case study guides the reader through the steps of drug development and opportunities for interacting with FDA, including:

- Nonclinical testing
- Investigational New Drug application content and submission
- Clinical trials and protection of human subjects
- New Drug Application content
- FDA inspections of manufacturing and clinical sites
- Post marketing requirements

How can it be used in a classroom environment?

Students read the case study before class. Discussion questions are provided to emphasize the major points of the case study. Exercises, activities and quizzes to reinforce learning are provided.

Is continuing education credit offered?

CME is currently not offered for the case study.

How can patients benefit?

The case study helps patients understand how drugs are developed and approved, and how to engage with FDA through the drug approval process.

Where can I get it?

This case study may be used and

Sample text

“Green and her colleagues now faced the task of beginning the clinical trials needed to obtain approval from the US FDA to market the drug.” “Can you give me a big picture overview of the drug development and approval process?” Soto asked.

Learning Objectives:

1. State the objectives of the drug development and approval process.
2. Identify the major activities that occur during the drug development and approval process from nonclinical tests through approval from the U.S. Food and Drug Administration (FDA).
3. Describe the major elements and steps to conduct a clinical trial.
4. Apply the drug approval process to a fictional New Molecular Entity (NME) diabetes drug.

Sample Student Activities

Questions for class discussion:

- What are the milestones in the drug development and approval process?
- Why is informed consent required for people participating in clinical studies?

Short Activities:

- You have been asked to develop a short presentation about the drug development and approval process for high school students attending a STEM (science, technology, engineering, and mathematics) conference. You will have 15 minutes to explain the process.
- A patient—who has struggled to manage his type 2 diabetes—shows you an article about a promising new drug for type 2 diabetes. He asks you why the drug is not available yet. You have 10 minutes to answer him.