

with respect to each patent that claims the listed drug, the patent is invalid or is not infringed by the generic product.

The current FDA Federal Food, Drug, and Cosmetic Act, with its subsequent amendments, is the basic food and drug law of the United States and is intended to assure consumers that foods are pure and wholesome, safe to eat, and produced under sanitary conditions; that drugs and devices are safe and effective for their intended uses; that cosmetics are safe and made from appropriate ingredients; and that all labeling and packaging are truthful, informative, and not deceptive. The mission of the FDA is to enforce laws enacted by the U.S. Congress and regulations established by the Agency to protect the consumer's health, safety, and pocketbook.

The Federal Register publishes a daily record of proposed rules, final rules, meeting notices, etc. (<http://www.access.gpo.gov/>). The final regulations are collected in the Code of Federal Regulations, or CFR (<http://www.access.gpo.gov/>). The CFR is divided into 50 titles representing broad areas subject to Federal regulations. The FDA's portion of the CFR interprets the Federal Food, Drug, and Cosmetic Act and related statutes. Title 21 of the CFR contains most of the regulations pertaining to food and drugs. The regulations document most actions of all drug sponsors that are required under Federal law.

## **GENERIC DRUG USER FEE AMENDMENTS OF 2012**

The generic drug industry has been very successful and has expanded globally. The volume of applications to the FDA has posed significant regulatory challenges and is straining limited public resources. With the increased volume of new generic drug applications, the time required for scientific review and inspections has lengthened along with a backlog of pending generic applications. Generic Drug User Fee Amendment of 2012 (GDUFA) is designed to speed the delivery of safe and effective generic drugs to the public and reduce costs to industry [8]. GDUFA aims to put the FDA's generic drug program on a firm financial footing and ensure timely access to safe, high-quality, affordable generic drugs. GDUFA enables the FDA to assess user fees to fund critical and measurable enhancements to the performance of the FDA's generic drugs program, bringing greater predictability and timeliness to the review of generic drug applications.

## **GENERIC DRUG APPROVAL**

The FDA's Office of Generic Drugs (OGD) is responsible for reviewing the ANDA and approving the drug product for marketing. The FDA's OGD has a website (<http://www.fda.gov/cder/ogd/>) that provides additional information for manufacturers of generic drug products that include an interactive flow chart presentation of the ANDA review process (Figure 1.2) and describes how the FDA determines the quality, safety, and efficacy of generic drug products before approval for marketing. Generic drug application reviewers focus on bioequivalence data, chemistry and manufacture, quality, microbiology data where relevant, requests for plant inspection, and drug labeling information. The FDA website is designed for individuals from pharmaceutical companies, government agencies, academic institutions, private