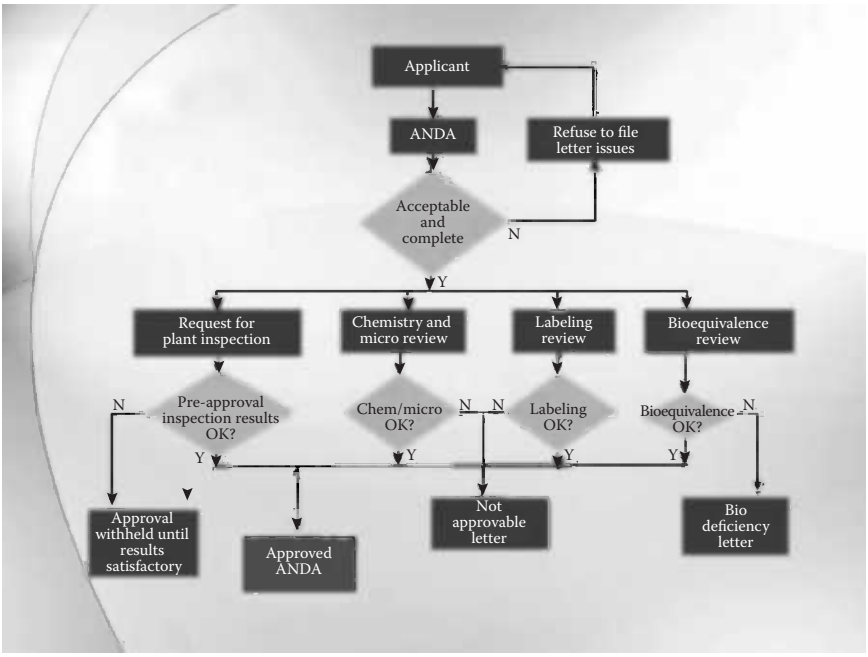

FIGURE 1.2 Generic drug review process.

organizations, or other organizations interested in bringing a generic drug product to market. Details of the FDA review and approval process are discussed in Chapter 9.

The ANDA is based on bioequivalence to the brand name product, appropriate chemistry and manufacturing information, and appropriate labeling. Generic drug sponsors do not have to duplicate the nonclinical animal toxicity studies or expensive clinical efficacy and safety studies that are included in the NDA, which is submitted to the FDA for market approval of the brand name drug product. The ANDA contains data, which, when submitted to the FDA's Center for Drug Evaluation and Research (CDER), Office of Generic Drugs (OGD), provide for the review and ultimate approval for marketing a generic drug product.

FDA-approved generic drugs must meet the same rigid standards as the innovator drug. To obtain FDA approval, a generic drug product must

- Contain the same active ingredients as an approved "RLD product" (generally, the innovator drug—the inactive ingredients may vary)
- Be identical in strength, dosage form, and route of administration
- Have the same use indications
- Be bioequivalent
- Meet the same batch requirements for identity, strength, purity, and quality
- Be manufactured under the same strict standards of the FDA's good manufacturing practice regulations as required for innovator products