The economic impact of the HWA is best demonstrated by the increased market share of generic medications. In 1984, just 14% of all prescriptions dispensed were for generic drugs. In contrast, 27 years later in 2011, approximately 78% of all prescriptions dispensed were for generic drugs. Furthermore, with the use of generic drugs, consumers save roughly $3 billion per week. Since the inception of HWA to date, generic drugs have saved the American healthcare system over $1 trillion.

The goal of this chapter is to provide an overview of the generic drug review process for solid oral dosage forms. Each step of the review process will be discussed from the initial submission of the application to its final approval. As one reads through the chapter, it may be useful to refer to the flow diagram given in Figure 9.1. Because the discussion is limited to the review of solid oral dosage forms, the microbiology review is omitted.

FILING REVIEW OF ANDA

The ANDA process begins when an applicant submits an ANDA to the OGD. The document room staff processes the ANDA, assigns it an ANDA number, and stamps a received date on the cover letter of the ANDA. The ANDA is then sent to a consumer safety technician, who reviews the preliminary sections of the ANDA checklist.

Within the first 60 days after the submission of an ANDA, a filing review is completed. The Regulatory Support Branch (RSB) is responsible for the filing review. This group, organized under the Division of Labeling and Program Support (DLPS), consists of project managers and a support staff, including technical information assistant(s), legal instruments examiner(s), and consumer safety technician(s). The branch chief who reports to the Division Director of DLPS supervises the branch.

The RSB ensures that the ANDAs contain the information necessary to merit a technical review. To determine whether an application is acceptable for filing, an RSB project manager (RPM) compares the contents of each section of the application (see Appendix 9.A) against a list of regulatory requirements. An applicant may receive a "refuse to receive" letter for a number of reasons. These include, but are not limited to, when an inactive ingredient level exceeds the level previously used in an approved drug product via the same route of administration, incomplete bioequivalence studies, incomplete stability data, incomplete packaging, and incorrect basis for submission. The filing date of an application is critical because it may determine the eligibility for exclusivity. The RSB verifies that all applications contain a patent certification and exclusivity statement. The patent certification and exclusivity statement must address all existing patents and exclusivities for the RLD published in the "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." If an RLD has expired patents, an applicant may certify that no relevant patents remain. The review of patents and exclusivities is an ongoing process throughout the review cycle, as new patents and exclusivities may become listed in the "Orange Book." An explanation of patent certifications with their corresponding definitions may be found in 21 CFR 314.94(a)(12).