RESOURCES FOR ANDA SUBMISSIONS

The FDA's CDER (http://www.fda.gov/cder) and the OGD (http://www.fda.gov/cder/ogd/) provide assistance to the sponsor of an ANDA to meet the legal and regulatory requirements of an application. FDA provides assistance through its website and publications, guidances, internal ANDA review principles, policies, and procedures. A few resources for ANDA and NDA drug product development are listed in Table 1.6.

Guidance Documents for ANDAs

Guidance documents represent the Agency's current thinking on a particular subject (http://www.fda.gov/cder/regulatory/default.htm). These documents are prepared for the FDA review staff and applicants/sponsors to provide guidelines to the processing, content, and evaluation/approval of applications and also to the design, production, manufacturing, and testing of regulated products. They also establish policies intended to achieve consistency in the Agency's regulatory approach and to establish inspection and enforcement procedures. Because guidances are not regulations or laws, they are not enforceable, either through administrative actions or through the courts. An alternative approach may be used if such an approach satisfies the requirements of the applicable statute, regulations, or both. The FDA has numerous guidances for industry that relate to ANDA content and format issues [9].

Manual of Policies and Procedures

Manuals of Policies and Procedures (MaPPs) provide official instructions for internal practices and procedures followed by CDER staff to help standardize the drug review process and other activities, both internal and external [10]. MaPPs define external activities as well. All MaPPs are available for the public to review to get a

TABLE 1.6
Selected FDA Resources for New (NDA) and Generic (ANDA) Drug Product Development

Adverse event reporting system (AERS)
Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book)
Bioequivalence recommendations for specific products
Bioresearch monitoring information system
Clinical investigator inspection list
Dissolution methods database
Drug establishment's current registration site
Drugs @ FDA Database
Inactive ingredient search for approved drug products
National drug code directory
Postmarket requirements and commitments
Approvals