better understanding of office policies, definitions, staff responsibilities, and procedures. MaPP documents to help prepare ANDAs are listed together on the CDER's Manual of Policies and Procedures Web page (http://www.fda.gov/cder/mapp.htm).

Freedom of Information

The 1996 amendments to the Freedom of Information Act (FOIA) mandate publicly accessible "electronic reading rooms" with the FDA FOIA response materials and other information routinely available to the public with electronic search and indexing features. Before submitting an FOIA request, the sponsor should check to see if the information is already available on the FDA's website (http://www.fda.gov/foi/foia2.htm). There is a search engine to help find information [11].

Additional Resources Regarding Drug Development

The FDA provides additional resources regarding drug development on its website (http://www.fda.gov/cder/ode4/preind/Gen_Additional_Resources.htm). These resources are summarized in Table 1.7.

Drug Master File

The Drug Master File (DMF) is a submission to the FDA that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drug substances. The submission of a DMF is not required by law or FDA regulation. Further information regarding DMFs is available in the CDER Guidance Document on Drug Master Files or 21 CFR 314.420 [12].

TABLE 1.7
General Information Regarding Drug Development

General FDA Information
Resources within FDA
External Resources—General
External Resources—Education
Review Jurisdiction of Drug Product Classes within ODE IV
Items of General Interest
CDER Guidance Documents/MaPPs
Federal Register
CFR Title 21
FDA Forms Distribution Page
International Conference on Harmonisation Documents
IND/NDA Jackets/Submission Covers
DMF Information