

Reading Materials and Resources

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U.S. Food and Drug Administration (www.fda.gov)

The New Drug Approval Process

<http://www.fda.gov/cder/handbook/develop.htm>

Interactive diagram that provides an overview of the drug approval process.

The CDER Handbook

<http://www.fda.gov/cder/handbook/index.htm>

Describes the approval process and gives overview of each stage in the IND and NDA review processes.

Drug Approval Application Process

<http://www.fda.gov/cder/regulatory/applications/default.htm>

Provides links to detailed descriptions of all aspects of the drug approval process. Also includes information about the approval of generic drug products and biological therapeutic products.

Pharmaceutical Research and Manufacturers of America (PhRMA) (www.phrma.org)

Research and Development-Drug Discovery

http://www.phrma.org/index.php?option=com_content&task=view&id=382&Itemid