



FDA Approval Packages

Summary and analysis of pivotal clinical drug trials, pharmacology, toxicology and pharmaceutical information in one comprehensive document

Pivotal studies within Approval Packages Identified and abstracted

Organized into standard format with Table of Contents

Rapid response to all requests



United States FDA Approval Packages contain the FDA's review and evaluation of approved New Drug Applications (NDAs) and Biological License Applications (BLAs).

Pertinent clinical safety and efficacy information is summarized and reviewed from pivotal and supportive studies. These studies are often not published elsewhere. Pharmacological, pharmaceutical, and toxicological data are also included.

Alternatively, a subscription to the *Iowa Drug Information Service* database provides access to all the FDA Approval Packages currently in the database.

Inquiries: A complete listing of all available FDA Approval Packages appears at http://www.uiowa.edu/~idis/FDA_Approval_List.htm. Contact our office for information on availability of Approval Packages not listed on this site.

Fees: Approval Packages are available on paper or CD-ROM. Prices for individual FDA Approval Packages are included on the website listed above.

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