New Drug Application (NDA)

Introduction

For decades, the regulation and control of new drugs in the United States has been based on the New Drug Application (NDA). Since 1938, every new drug has been the subject of an approved NDA before U.S. commercialization. The NDA application is the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the U.S. The data gathered during the animal studies and human clinical trials of an Investigational New Drug (IND) become part of the NDA.

The goals of the NDA are to provide enough information to permit FDA reviewer to reach the following key decisions:

- Whether the drug is safe and effective in its proposed use(s), and whether the benefits of the drug outweigh the risks.
- Whether the drug's proposed labeling (package insert) is appropriate, and what it should contain.
- Whether the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity.

The documentation required in an NDA is supposed to tell the drug's whole story, including what happened during the clinical tests, what the ingredients of the drug are, the results of the animal studies, how the drug behaves in the body, and how it is manufactured, processed and packaged. The following resources provide summaries on NDA content, format, and classification, plus the NDA review process:

Resources for NDA Submissions

The following resources have been gathered to provide you with the legal requirements of a new drug application, assistance from CDER to help you meet those requirements, and internal NDA review principles, policies and procedures.

Guidance Documents for NDAs

Guidance documents represent the Agency's current thinking on a particular subject. These documents are prepared for 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 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 approach satisfies the requirements of the applicable statute, regulations, or both. For information on a specific guidance document, please contact the originating office.

For the complete list of CDER guidances, please see the Guidance Index. For information on a specific guidance document, please contact the originating office.

Guidance documents to help prepare NDAs:.

- Bioavailability and Bioequivalence Studies Submitted in NDAs or INDs and General Considerations
- Changes to an Approved NDA or ANDA
- Changes to an Approved NDA or ANDA: Questions and Answers
- Container Closure Systems for Packaging Human Drugs and Biologics
- Format and Content of the Microbiology Section of an Application,
- Format and Content of the Clinical and Statistical Sections of an Application
- Summary for New Drug and Antibiotic Applications--Format and Content of the Summary for New Drug and Antibiotic Applications
- Formatting, Assembling and Submitting New Drug and Antibiotic Applications,
- GUIDELINE FOR SUBMITTING SUPPORTING DOCUMENTATION IN DRUG APPLICATIONS FOR THE MANUFACTURE OF DRUG PRODUCTS
- NDAs: Impurities in Drug Substances
- Format and Content of the Human Pharmacokinetics and Bioavailability Section of an

Application

- Format and Content of the Nonclinical Pharmacology/Toxicology Section of an Application
- Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products
- Drug Master Files: Guidelines
- FDA IND, NDA, ANDA, or Drug Master File Binders
- PET Drug Applications - Content and Format for NDAs and ANDAs — 2011

Laws, Regulations, Policies and Procedures

The mission of FDA is to enforce laws enacted by the U.S. Congress and regulations established by the Agency to protect the consumer's health, safety, and pocketbook. *The Federal Food, Drug, and Cosmetic Act* is the basic food and drug law of the U.S. With numerous amendments, it is the most extensive law of its kind in the world. The law is intended to assure consumers that foods are pure and wholesome, safe to eat, and produced under sanitary conditions; that drugs and devices are safe and effective for their intended uses; that cosmetics are safe and made from appropriate ingredients; and that all labeling and packaging is truthful, informative, and not deceptive.

Code Of Federal Regulations (CFR)

The final regulations published in the *Federal Register* (daily published record of proposed rules, final rules, meeting notices, etc.) are collected in the *CFR*. The *CFR* is divided into 50 titles which represent broad areas subject to Federal regulations. The FDA's portion of the *CFR* interprets the *Federal Food, Drug and Cosmetic Act* and related statutes. Section 21 of the *CFR* contains all regulations pertaining to food and drugs. The regulations document all actions of all drug sponsors that are required under Federal law.

- 21CFR Part 314 - Applications for FDA Approval to Market a New Drug or an Antibiotic Drug.

CDER's Manual of Policies and Procedures (MaPPs)

These documents are approved instructions for internal practices and procedures followed by CDER staff to help standardize the new drug review process and other activities. MaPPs define external activities as well. All MaPPs are available for the public to review to get a better understanding of office policies, definitions, staff responsibilities and procedures.

MaPPS of particular interest to NDA applicants

- Review of the Same Supplemental Change to More than One NDA or ANDA in More Than One Review Division
- NDAs and BLAs: Filing Review Issues
- Action Packages for NDAs and Efficacy Supplements

- Refusal to Accept Application for Filing From Applicants in Arrears
- Requesting and Accepting Non-Archivable Electronic Material for CDER Applications

Prescription Drug User Fee Act (PDUFA)

On November 21, 1997, The President signed the Food and Drug Administration Modernization Act of 1997. This legislation includes authorization for FDA to continue to collect three types of user fees from applicants who submit certain new drug and biological product applications. FDA was first authorized to collect user fees under the Prescription Drug User Fee Act (PDUFA) of 1992.

- Prescription Drug User Fee Act Related Documents

NDA Forms and Electronic Submissions

- Form FDA-356h. Application to Market a New Drug, Biologic, or An Antibiotic Drug For Human Use
    - Form FDA-356h instructions
- Form FDA-3397. User Fee Cover Sheet
- Form FDA-3331. New Drug Application Field Report
- Guidance Documents for Electronic Submissions
- For more information on electronic submissions, see Electronic Regulatory Submissions and Review Helpful Links.

Advisory Committees

Advisory committees provide independent advice and recommendations to the FDA on scientific and technical matters related to the development and evaluation of products regulated by the Agency. CDER requests advice from advisory committees on a variety of matters, including various aspects of clinical investigations and applications for marketing approval of drug products. Committee members are scientific experts such as physician-researchers and statisticians, as well as representatives of the public, including patients. Although the committees provide recommendations to the Agency, final decisions are made by FDA.

- FDA Advisory Committees
- CDER Advisory Committees
- CFR 21 Part 14 Public Hearing Before a Public Advisory Committee. Detailed description of advisory committees from the *Code of Federal Regulations*.
- Guidance for Industry: Advisory Committees. Includes information on membership, conflict of interest, scheduling, and action on recommendations.

- Advisory Committee Meeting Calendar. Several dates have been set aside by CDER advisory committees for possible future meetings. The subject matter and location of the meetings (if they are held) will be published in the *Federal Register* in the month prior to the meeting date.

Related Topics

- 21st Century Cures Act
- Electronic Regulatory Submissions and Review Helpful Links
- Information for Clinical Investigators (INDs)
- CDER Small Business and Industry Assistance
- Surveillance: Post Drug-Approval Activities

Resources For You

- Investigational New Drug (IND) Application
- Investigator-Initiated INDs
- Therapeutic Biologic Applications (BLA)
- Abbreviated New Drug Application (ANDA): Generics

Content current as of:
06/10/2019