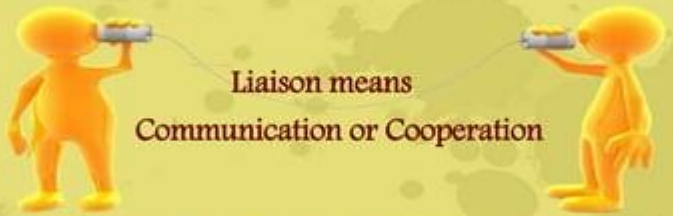
INTRODUCTION



Liaison means

Communication or Cooperation

- The FDA is one of our nation's oldest consumer protection agencies.
- FDA is a public health agency, charged with protecting American consumers by enforcing the Federal Food, Drug, and Cosmetic Act and several related public health laws.
- There is approximately 9,000 employees who monitor the manufacture, import, transport, storage, and sale of about $1 trillion worth of products each year.
- These employees are located in district and local offices in 157 cities across the country.

Missions of FDA

- Inspections and Legal Sanctions
- Scientific Expertise
- Product Safety

Inspections and Legal Sanctions

- The investigators and inspectors visit more than 16,000 facilities a year, seeing that products are made correctly and labeled truthfully.
- They collect about 80,000 domestic and imported product samples for examination by FDA scientists or for label checks.
- If a company is found violating any of the laws, the FDA can encourage the firm to correct the problem voluntarily or to recall a faulty product from the market.
- When a company cannot or will not voluntarily correct a public health problem with one of its products, the FDA has legal sanctions it can bring to bear.

Scientific Expertise

- The scientific evidence needed to back up the FDA's legal cases is prepared by the agency's 2,100 scientists, including 900 chemists and 300 microbiologists.
- Some of these scientists analyze samples and others review test results submitted by companies seeking agency approval for drugs, vaccines, food additives, coloring agents, and medical devices.
- The agency must determine that the new drug produces the benefits it is supposed to without causing side effects that would outweigh those benefits.

Product Safety

- The agency's scientists test samples to see if any substances, such as pesticide residues, are present in unacceptable amounts.
- If contaminants are identified, the FDA takes corrective action.
- The safety of the nation's blood supply is another FDA responsibility. The agency's investigators routinely examine blood bank operations, from record-keeping to testing for contaminants.
- Cosmetic safety also comes under the FDA's jurisdiction. The agency can have unsafe cosmetics removed from the market.

FDA DIVISIONS

- **CDER** — Center for Drug Evaluation and Research
- **CBER** — Center for Biologics Evaluation and Research
- **CDRH** — Center for Devices and Radiologic Health
- **CFSAN** — Center of Food Safety and Applied Nutrition
- **CVM** — Center for Veterinary Medicine
- **NCTR** — National Center for Toxicological Research

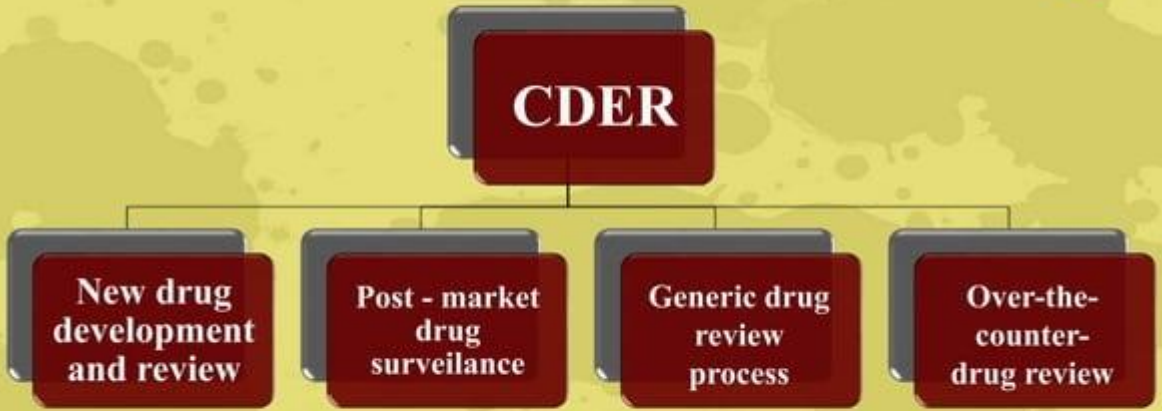
CENTER FOR DRUG EVALUATION AND RESEARCH

- CDER's mission is to ensure that safe and effective prescription, non-prescription and generic drugs are available to the people as quickly as possible.
- CDER fulfills its mission by overseeing the clinical research, development, manufacture, and marketing of drugs.
- As of August 2003, there are 15 review divisions within CDER that are responsible for reviewing all INDs, NDAs, and chemistry and efficacy supplemental applications.
- CDER ensures that drug labeling, drug information for patients, and drug promotion are truthful, helpful, and not misleading.

FUNDAMENTAL GOALS AND OBJECTIVES

- **Promote public health by ensuring the availability of safe and effective drugs:** Promote patient and health professional awareness of drug benefits and risks through effective communication of drug information.
- **Protect public health by promoting the safe use of marketed drugs:** Oversee drug promotion and marketing to help ensure that marketed drug labeling and advertising are truthful and not misleading.
- **Protect public health by ensuring the quality and integrity of marketed drug products.**

CDER ORGANIZATION



- The Office of Pharmaceutical Science (OPS) is an integral part of CDER's new and generic drug product application review process.
- The goal of OPS is to help establish common approaches to the manufacture and formulation of drugs among pharmaceutical manufacturers.
- OPS has four main offices:

Office of Generic Drugs

Office of New Drug Chemistry

Office of Clinical Pharmacology and Biopharmaceutics

Office of Testing and Research

CONTACTS WITH THE FDA

- One of CDER's primary goals is to work collaboratively and cooperatively with industry, to improve the drug development and review process.
- It also strives to provide consumers and health care providers with drug information that is vital for improving the public health.
- The various means of communicating with the CDER are:
  - Consumer/Industry Inquiries.
  - Industry/FDA Inquiries.
  - FDA/Industry Meetings.

Consumer/Industry Inquiries

- To enhance the communications aspect of this process, the Center created the Division of Communications Management (DCM).
- This division enhances information exchange, strategic communications planning, and the development of communications products and initiatives.
- The Division of Communications Management works to ensure that pharmaceutical industry representatives, health care professionals, government officials, and consumers have easy and open access to information and are educated about the drug regulation process and the benefits and risks of drugs.

- There are a number of ways consumers and industry representatives can communicate with the Center or get reliable, current, and up-to-date information from it.
  - The newest and easiest method for getting information is the Center's world wide web homepage at http://www.fad.gov/cder.
  - For more specific or complex drug inquiries, individuals may telephone the Drug Information Branch or send an electronic mail.
  - For specific inquiries from industry, CDER's Compendia Operations

Industry/FDA Inquiries

- All meetings with the FDA are held at the pleasure of the agency and should be requested judiciously.
- Project managers , are responsible for coordinating FDA/industry meetings.
- If a meeting with the FDA is deemed necessary, the first step is to telephone the project manager assigned to the firm's IND or NDA.
- The need for a meeting should be explained, a statement about the general topic of the meeting should be described, and an idea of when the meeting is needed should be offered.

- The project manager will likely return the call and indicate if a meeting will be granted.
- If the answer is positive, a confirmatory letter from the firm should be sent to the appropriate division.
- The document should include the fact that the meeting has been granted and what the date for the meeting will be.
- The names and titles of those representatives of the sponsor who will be attending the meeting, and the proposed agenda are provided.

FDA/Industry Meetings

- There are three types or categories of meeting that industry can request to the agency.
- They are typically known as Type A, B, or C meetings.

TYPE A

- **Most important.**
- **To dispute issues that arise during new drug development, or to resolve clinical holds that the FDA has deemed necessary.**
- **These meetings are usually scheduled 30 days from FDAs receipt of a written request for a meeting.**

TYPE B

- Usually occur for a pre-ind, an end of phase 1 (EOP1), an end of phase 2 (EOP2), a pre phase 3, or a pre-nda or BLA. All of these meetings will be honored by the FDA.
- Usually scheduled 60 days from the time the agency received the written request.

TYPE C

- Any other meeting not falling into type A or B meetings.
- These are meetings that pertain to the review of human drug applications.
- These meetings are usually scheduled within 75 days of the agency's of the written request.

Pre-IND/Preclinical Meetings

- Prior to clinical studies, the sponsor needs to demonstrate evidence that the compound is biologically active.
- Preclinical meetings are occasionally conducted with the appropriate division that would review the IND or the drug marketing application, and these meetings are typically requested by the sponsor of a drug.
- Meetings at such an early stage in the process are sometimes useful for open discussion about testing phases, data requirements, and any scientific issues that may need to be resolved prior to IND submission.

End-of-Phase 2 Meeting (EOP2)

- The primary focus of "end-of-phase 2" meetings is to determine whether it is safe to begin phase 3 testing.
- This is also the time to plan protocols for phase 3 human studies and to discuss and identify any additional information that may be required to support the submission of an NDA.
- These meetings avoid unnecessary expenditures of time and money because data requirements have been clarified.
- One month before the end-of-phase 2 meeting, the sponsor should submit the background information and summary protocols for phase 3 studies.

Pre-NDA Meetings

- The purpose of a pre-NDA meeting is to discuss the presentation of data (both paper and electronic) in support of the application.
- The information provided at the meeting by the sponsor includes:
  - A summary of clinical studies to be submitted in the NDA.
  - The proposed format for organizing the submission, including methods for presenting the data.
  - Other information that needs to be discussed.

Advisory Committee Meetings

- Advisory committees have been established to advise and make recommendations on issues related to the agency's regulatory responsibilities.
- The primary role of FDA advisory committees is to provide independent expert scientific advice to the agency, and to help make sound decisions based on the reasonable application of good science.
- The committees are advisory in nature, and final decisions are made by the FDA.
- Advisory committee meetings can be very advantageous to sponsors who are filing an NDA for similar drug categories.

FDA INITIATIVES TO SPEED UP DRUG APPROVAL PROCESS

- The FDA has instituted several programs designed to hasten the drug approval process for effective drugs.
- The FDA pathways to swift new drug approval are:

- Accelerated Development/Review Program
- Treatment IND
- FDA Guidance Documents/Guideline

Accelerated Development/Review Program

- Accelerated development/review is a highly specialized mechanism for speeding the development of drugs that promise significant benefit over existing therapy for serious or life-threatening illnesses.
- This process incorporates several novel elements aimed at making sure that rapid development and review are balanced by safeguards to protect both the patient and the integrity of the regulatory process.

Treatment IND

- Treatment INDs are used to make promising new drugs available to desperately ill patients as early in the drug development process as possible.
- The FDA will permit an investigational drug to be used under a treatment IND if there is preliminary evidence of drug efficacy and the drug is intended to treat a serious or life-threatening disease.
- Treatment INDs are made available to patients before general marketing begins, typically during phase 3 studies.
- Treatment INDs also allow the FDA to obtain additional data on the drug's safety and effectiveness.

FDA Guidance Documents/Guidelines

- A regulatory professional must be aware of the guidance documents that the FDA has made available to assist industry to understand expectations regarding drug development and the approval process.
- The website providing the complete list of FDA guidance's is updated almost daily.
- The FDA comprehensive list of all guidance's available is found on the internet.

FREEDOM OF INFORMATION ACT (FOIA)

- Freedom of information is another important way in which regulatory personnel may readily obtain information from the FDA.
- The FDA has published a guidance handbook intended to facilitate requests for both public information and records not originally prepared for distribution by the FDA.
- This handbook has been updated in response to the Electronic Freedom of Information Act (FOIA) amendments of 1996

Obtaining Information Through the FOI

- The Freedom of Information Act allows anyone to request copies of records not normally prepared for public distribution.
- It pertains to existing records only and does not require agencies to create new records to comply with a request.
- It also does not require agencies to collect information they do not have or to do research or analyze data for a requestor.
- In addition, FOI requests must be specific enough to permit an FDA employee who is familiar with the subject matter to locate records in a reasonable period.

How to Make an FOI Request

- All FOI requests must be in writing and should include the following information:
  - Requestor's name, address, and telephone number.
  - A description of the records.
  - Separate requests should be submitted for each firm or product involved.
  - A statement concerning willingness to pay fees, including any limitations.
- All FOI requests must be in writing. The FDA does not accept FOI requests sent by email.

Fees

- Requestors under FOIA may have to pay fees covering some or all of the costs of processing their request.
- Requestors may want to include the maximum dollar amount they are willing to pay.
- If the fees exceed the maximum amount stated, FDA will contact the requestor before filling the request.
- Requestors are generally billed for fees after their requests have been processed.

SUMMARY

- All dealings with the FDA or other regulatory agencies for that matter must be well conceived and adequately planned.
- Without knowledge, conception, planning, and an understanding of how the other half works, significant delays in drug approval frequently and painfully occur.
- Whether the regulatory goal is to speed the approval process for a new product or to keep a product on the market, the firm must know how bet to work with the FDA.