

INDUSTRY AND FDA LIAISON

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INTRODUCTION

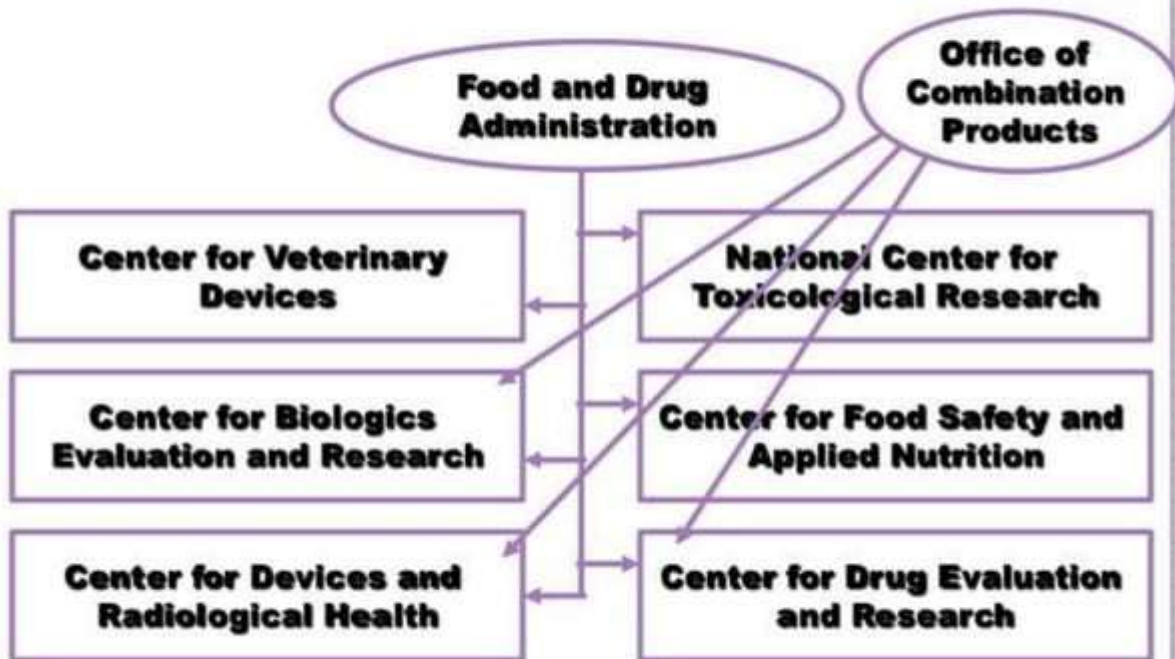
- **Experienced Drug Regulatory Affairs [DRA] personnel are essential in the process of new product development.**
- **They are largely responsible for establishing a liaison with their counterparts at the U.S. Food and Drug Administration [FDA] and other regulatory agencies globally.**
- **FDA is one of our nations oldest consumer protection agencies dating back to 1862.**

U.S. FDA

- The U.S. FDA [Food and Drug Administration] is an agency of the US Department of Health and Human services [DHHS] that is responsible for the safety regulation of :
 - most type of foods
 - vaccines
 - drugs
 - Blood products
 - dietary supplements
 - biological medical products
 - cosmetics

- The FDA also enforces other laws ,notably **Section 361** of the **Public Health service Act** and associated regulations, many of which are not directly related to food or drugs
- They include **sanitation** requirements on **interstate travel** and control of disease on products ranging from certain household **pets** to **sperm donation** for **assisted reproduction**.
- The FDA has its **headquarters** at **White oak, Maryland** . The agency also has **223 field offices** and **13 laboratories** located throughout **50 states**.

FDA Structure / Organization



Responsibility of FDA organization

FDA Center	Areas of Responsibility
Center for Drug Evaluation and Research	Safety and effectiveness of Rx and over the counter drugs
Center for Biologics Evaluation and Research	Safety and effectiveness of vaccines, nations blood supply, other biologics
Center for Devices and Radiological Health	Safety and effectiveness of medical devices, diagnostic tests, radiation emitting devices
Center for Food Safety and Applied Nutrition	Safety of domestic and imported food supply, cosmetics, dietary supplements
Center for Veterinary Medicine	Safety and effectiveness of veterinary drugs
Center for Tobacco Products	Implementation of the Family Smoking Prevention and Tobacco Control Act
National Center for Toxicological Research	Research to support regulatory decisions and reduce risks associated with FDA-regulated products
Office of Regulatory Affairs	Enforcement of laws and regulations

Who Makes Up the FDA?

- † The FDA consists of employees drawn from a wealth of science and public health professions.
- † Biologists, physicians, chemists, biomedical engineers, toxicologists, pharmacologists, veterinarians, and specialists in the public health education and communication.
- † FDA employs approximately 11,516 people who work in locations around the United States.

FDA Advisory Committee

- ↑ They provide FDA with independent advice from outside experts on issues related to human and veterinary drugs, vaccines and other biological products, medical devices, and food.
- ↑ In general, advisory committees include a chair, several members, plus a consumer, industry, and sometimes a patient representative.
- ↑ Additional experts with special knowledge may be added for individual committee meetings as needed. although the committees provide advice to the agency, FDA makes the final decisions.

FDA Initiatives to Speed Drug Approval

- The FDA has instituted several programs designed to hasten a drug approval process for effective drugs.
- FDA Alternative to expedite new drug approval are described below
- Subpart E Section 312 of the code of federal regulations establishes procedures to expedite the development , evaluation , and marketing of new therapies intended to treat people with life threatening and severely debilitating illnesses [Debilitating comes from the Latin word debilis, meaning “weak”] especially where no satisfactory alternative exist .

FDA Guidance Documents/Guidelines

- A regulatory professional must be aware of the guidance documents that 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 Guidances is updated almost daily .
- It may be accessed at <http://www.fda.gov/cder/guidance/index.htm>.

SUMMARY

- **FDA and Sponsor Liaison is an art that is developed over years of experience gained from understanding Regulations , guidelines , and recommendation from regulatory experts.**
- **It is vital that regulatory personnel attend meetings, conferences , and courses of all aspects of regulatory issues on the process of new product development.**

- **A knowledge of how global regulatory agencies operate is essential to the success of a DRA department.**
- **All dealings with the regulatory agencies must be well conceived and adequately planned.**
- **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 best to work with all regulatory agencies involved.**

REFERENCES

- **NEW DRUG APPROVAL PROCESS** fifth edition
by Richard A. Guarino , M.D.
- **INTERNET SOURCE**

THANK YOU