Understanding the Organization and Function of the FDA

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The United States regulatory authority can be a complicated system to negotiate. The Food and Drug Administration’s (FDA) mandate, responsibilities, and structure will be reviewed. General topics related to drugs, devices, and biologics will be explored. Orphan product development and grant funding will be discussed. Issues of particular interest to new investigators will be raised with specific emphasis on locating needed information and working with the agency throughout the drug/device/biologic development process.

Introduction

The U.S. FDA is one of the agencies of the Public Health Service (PHS) and falls under the umbrella of the Department of Health and Human Services (DHHS). The FDA is headed by the commissioner, David A. Kessler, and is responsible for ensuring that foods are safe and wholesome; that human and veterinary drugs, human biological products, and medical devices are safe and effective; that cosmetics are safe; and that consumer products that emit radiation are safe. The agency also ensures that regulated products are honestly, accurately, and informatively represented; that noncompliance with regulations and guidelines is identified and corrected; and that any unsafe or unlawful products are removed from the marketplace.

In order to accurately and adequately present the topic as charged (“Understanding the Organization and Function of the FDA”), this chapter would need to review each branch and twig of a complicated organizational tree and review issues ranging from legislative affairs, policy, and management to concerns surrounding veterinary medicine approvals and food safety. Instead, this paper will present and discuss the organization of the agency as seen from a new investigator’s position and will address issues concerning product development in each of the relevant centers (drug,
biologic, and device) and offices (orphan products as well as several of the offices that make up "external affairs"), along with an example of the review “team” process as employed in one of the centers—the Center for Drug Evaluation and Research (CDER).

The Center for Drug Evaluation and Research

This center's mission is to approve drugs for marketing that are effective for their labeled indications, provide benefits that outweigh risks, are of high quality, and have directions for use that are complete and honestly communicated. The CDER must also facilitate early access to promising experimental drugs being developed for serious illnesses with no adequate therapy; promote innovation and provide assistance in the drug development process; ensure that the safety and rights of patients in drug studies are adequately protected; and ensure that product quality and safety are maintained after marketing.

The center is made up of several offices and divisions. The offices most closely involved with primary investigational new drug (IND) applications and new drug applications (NDAs) review include the Office of Drug Evaluation I and the Office of Drug Evaluation II. Several other offices provide further expertise in the review process, for example, the Office of Epidemiology and Biostatistics, the Office of Generic Drugs, and the Office of Compliance.

In the review of most FDA-regulated products, the review is performed simultaneously by members of a review “team.” In the CDER, the team is made up of chemists, pharmacologists, physicians, statisticians, and others (microbiologists, biopharmacologists, etc.) as appropriate. The review team also incorporates a consumer safety officer (CSO) or “project manager” who provides regulatory guidance to sponsors (industry, investigators, etc.) and to the review team; manages projects (INDs and NDAs, for example); and serves as a conduit for information between industry (or investigators, consumers, etc.) and the review team and among review team members.

The Offices of Drug Evaluation are made up of several divisions with responsibility for specific drug groups. Questions regarding product development should be directed to the appropriate division, and within that division, the CSO (or project manager) assigned to the specific drug. Phone numbers are included at the end of this paper to assist in obtaining necessary information for negotiating the system most efficiently and effectively.

The Center for Biologics Evaluation and Research

Since 1970, the PHS Act has defined a “biologic” as a “virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product . . .” (1).