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Review on Food and Drug Administration

Pratiksha. K. Budhbaware, Rashmi Sonkusare, Chaitalee Girde, Prajwal Wankhade
New Montfort Institute of Pharmacy, Ashti, Wardha, Maharashtra, India
pratikshabudhabaware49@gmail.com

Abstract: *Clinical trial evidence used to support drug approval is typically the only information on benefits and harms that patients and clinicians can use for decision-making when novel cancer therapies become available. Various evaluations have raised concern about the uncertainty surrounding these data, and a systematic investigation of the available information on treatment outcomes for cancer drugs approved by the US Food and Drug Administration (FDA) is warranted. Indeed drug delivery system should be designed to provide a therapeutic agent in the needed amount, at the right time to the proper location in the body, in a manner that optimizes efficacy, increases compliance and minimizes side effects. A well designed controlled drug delivery system can overcome some of problems of conventional therapy and enhance therapeutic efficacy of the given drug. The US Food and Drug Administration (FDA) oversees safety and efficacy of a broad spectrum of medical products (ie, drugs, biologics, and devices) under the auspices of federal legislation and agency regulations and policy.*

Keywords: Expanded access, Immediately life-threatening Disease, Industry, Investigator, Sponsor.

I. INTRODUCTION

The Food and Drug Administration (FDA) oversees the approval and regulation of drugs entering theU.SMarket.
Two regulatory frameworks support the FDA's review of prescription drugs. First, FDA reviews the safety and effectiveness of new drugs that manufacturers wish to market in the United States; this process is called *premarket approval* or *preapproval review*. Second, once a drug has passed that threshold and is FDA-approved, FDA acts through its *post market* or *post-approval* regulatory procedures. This report is a primer on drug approval and regulation. [1] it describes how drugs are approved and come to market, including FDA's role in that process and FDA and industry roles once drugs are on the pharmacy shelve.. [2]
The Food and Drug Administration (FDA) is responsible for assuring that foods and cosmetics are safe and that medicines and medical devices are both safe and effective. To carry out this responsibility, the FDA monitors more than $1 trillion worth of products, representing about $0.25 of every $1.00 spent annually by American consumers. Balancing the efficacy and safety of these products is the core public health protection duty of the FDA. This mission requires examining efficacy as determined from well-controlled trials, effectiveness as determined from actual use in uncontrolled settings, and safety for both prescription and over the-counter pharmaceuticals before approving a medication for market.[3]

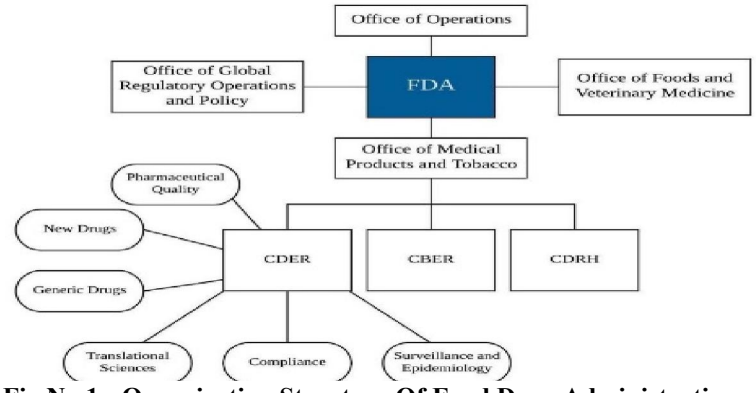

Fig No 1: Organization Structure Of Food Drug Administration

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Structure of FDA[12]

- CBER – Biologics, vaccines, blood, cells/genes
- CDER – Drugs, Rx and OTC, Advertisements
- CDRH – Devices and radiation emitting products
- CFSAN – Food safety, not meat poultry & eggs
- CTP – Tobacco product labelling and ads
- CVM – Animal food and drug safety and effectiveness
- ORA – Quality system compliance
- NCTR – Counter terrorism, pathogen monitoring

ROLE OF FDA:

1) FDA is a component of the Department of Health and Human Services but traditionally has functioned with a high degree of independence (but, at the same time, with many checks and balances, or" safeguards, "to assure public accountability and prevent official abuse of authority).

2) FDA's regulatory autonomy rests upon three pillars: strong legal underpinnings, a solid basis in science and public health protection for its decisions, and support of the public.

3) Concerning the legal underpinnings, FDA administers and enforces comprehensive laws to assure that food and cosmetics are safe, that pharmaceuticals and medical devices have been shown by the manufacturer to be safe and effective, and that all products are properly labelled.

4) Its institutional semi-autonomy is aided by the statutory provisions that provide for an agency charter, as well as regulations that delegate to the Commissioner (from the Secretary of Health and Human Services) virtually all authority under the statutes FDA administers. [4]

LIMITATION [5]

- We did not independently verify the COMIS data or the OGD consult data to ensure their accuracy. Almost all original ANDAs are disapproved because Chemistry finds deficiencies.
- Therefore, we determined the extent to which original ANDA review times exceeded the 180-day review clock by analysing Chemistry review times.
- We did not determine the extent to which original ANDA review times exceeded the 180-day review clock in other divisions when Chemistry did not find deficiencies.
- The results from our sample of 105 ANDAs with review times greater than 180 days are not projectable.
- Shorter ANDA review times cannot be directly linked to faster market entry because of valid patents or exclusivities or applicants' marketing decisions.
- For example, an ANDA can be approvable by all divisions within 180 days, but valid patents or exclusivities prevent OGD from approving the ANDA.
- OGD can only tentatively approve ANDAs before valid patents or exclusivities expire.
- Once OGD approves ANDAs, applicants' marketing decisions may further delay or prevent drugs' market entry.

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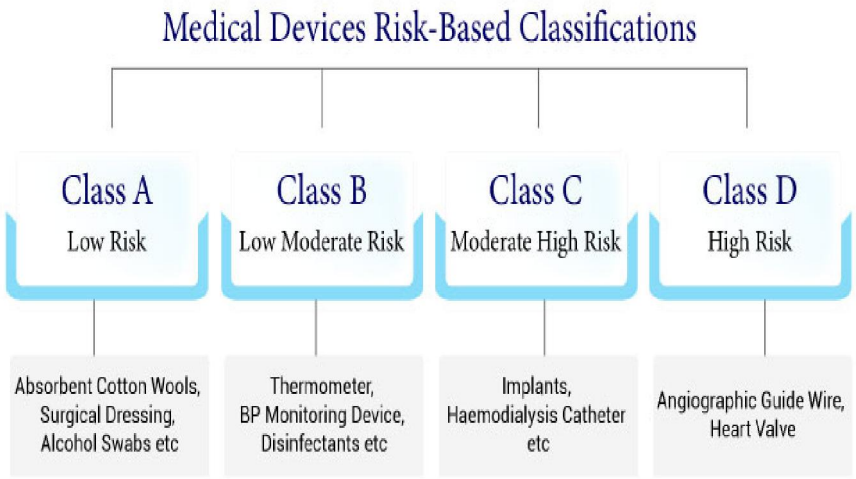

Fig no 2 : Medical Device Classification

How FDA Approves New Drugs

To market a prescription drug in the United States, a manufacturer needs FDA approval. To get that approval, the manufacturer must demonstrate the drug's safety and effectiveness according to criteria specified in law and agency regulations, ensure that its manufacturing plant passes FDA inspection, and obtain FDA approval for the drug's labeling—a term that includes all written material about the drug, including, for example, packaging, prescribing information for physicians, and patient brochures.[6]

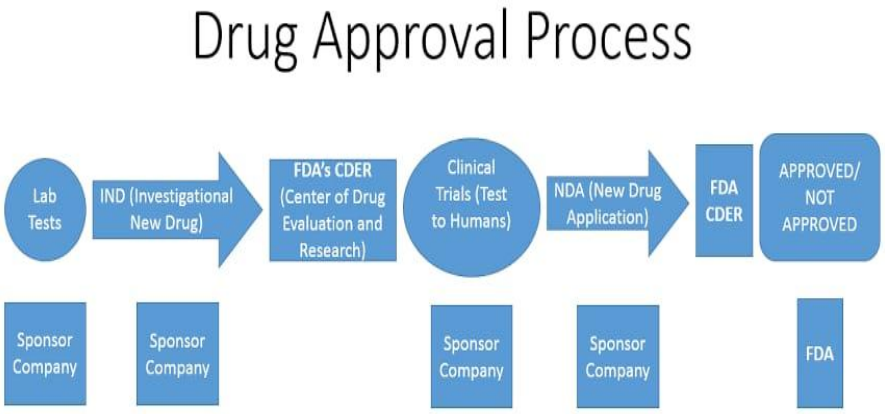

Fig N : 3

The Standard Process of Drug Approval

The four FDA steps leading to the agency's approval of a new drug for marketing in the United States are described below. This report describes the process for a new drug. For a generic drug— one that is chemically and therapeutically identical to an already approved drug—the process is abbreviated.[7]

Investigational New Drug (IND) Application

Except under very limited circumstances, FDA requires data from clinical trials—formally designed, conducted, and analyzed studies of human subjects—to provide evidence of a drug's safety and effectiveness. Before testing in

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humans—called clinical testing—the drug's sponsor (usually its manufacturer) must file an investigational new drug (IND) application with FDA. The IND includes information about the proposed clinical study design, completed animal test data, and the lead investigator's qualifications.[8]

Fig no : 4 Types IND

Clinical Trials

With IND status, researchers test in a small number of human volunteers the safety they had demonstrated in animals. These trials, called Phase I clinical trials, attempt, in FDA's words, "to determine dosing, document how a drug is metabolized and excreted, and identify acute side effects." If the sponsor considers the product still worthy of investment, it continues with Phase II and Phase III clinical trials[9]

- **Phase 1:** The drug is tested in 20 to 100 healthy volunteers to determine its safety at low doses. About 70% of candidate drugs advance to Phase 2.
- **Phase 2:** The drug is tested for both efficacy and safety in up to several hundred people with the targeted disease. Some two-thirds of candidate drugs fail in Phase 2 clinical trials due to the drug not being as effective as anticipated.
- **Phase 3:** The drug is typically tested in several hundred to several thousand people with the targeted disease in double-blind, placebo controlled trials to demonstrate its specific efficacy. Under 30% of drug candidates succeed through Phase 3.
- **Phase 4:** These are postmarketing surveillance trials in several thousand people taking the drug for its intended purpose to monitor efficacy and safety of the approved marketed drug. [10]

New Drug Application

The Food and Drug Administration's (FDA) **New Drug Application** (**NDA**) is the vehicle in the United States through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing. Some 30% or less of initial drug candidates proceed through the entire multi-year process of drug development, concluding with an approved NDA, if successful.The goals of the NDA are to provide enough information to permit FDA reviewers to establish the complete history of the candidate drug. Among facts needed for the application are: [11]

FDA Mission[12]

- Protect public health
- Safety efficacy and security of approved drugs, devices, biologics, cosmetics, and food supply.
- Advancing public health
- Sharing information

FDA Related Agencies

- FTC -false advertisement

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- CMS – Medicare and Medicaid reimbursement
- CPSC – product safety
- SEC – protect investing public
- OSHA – employee safety
- TTB - alcohol safety
- USDA – dairy, poultry, fruit,and meat safety
- DOC – fish safety
- EPA – environment protection
- DEA – illegal drugs

Drugs:

Alpha Hydroxy Acids

Alpha hydroxy acids (AHAs) also represent a crossover between cosmetics and drugs. The typical effects of alpha hydroxy acids have been described as follows: Alpha hydroxy acids are basically chemical versions of facial scrubs. When applied topically, they slough off the dead cells of the skin's top layer, forcing the underlying cells to create fresh new cells to replace them. The body may also attempt to repair this minor "damage" by depositing new collagen in the underlying, dermal layer. The result is smoother, firmer, more evenly pigmented skin. [13]

Beta-Hydroxy Acids

Within the past year, beta hydroxy acids (BHAs) have leaped ahead of AHAs as the hot new unregulated cosmeceutical for wrinkle reduction, with potential adverse economic and physical effects to the consumer. Typical of most cosmetics and cosmeceuticals, the published efficacy research on BHAs (specifically, the effectiveness of salicylic acid for safely reducing wrinkles) is negligible at best. According to one study, salicylic acid (the primary ingredient in all BHA formulations) was more effective at just one-fifth the concentration of glycolic acid (an AHA formulation ingredient), with less potential for skin irritation than that caused by glycolic acid.[14]

II. CONCLUSION

The FDA is strengthening its post marketing surveillance system with new staff and resources in order to meet the challenges of the changing world of therapeutic ensuring the safety and effectiveness of drugs on the market however, is a responsibility that the FDA shares with industry , all health care professional including physician and pharmacist and patients .The FDA's success in reducing drug related adverse event depends to a large extent on the adverse event reports its received from health care professional, either directly or through the manufactures . New drugs are an important part of modern medicine. Just a few decades ago, a disease such as peptic ulcers was a frequent indication for major surgery. The advent of new pharmacologic treatments has dramatically reduced the serious complications of peptic ulcer disease.

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