"Exploring The US-FDA Approved Pharmaceutical Drug Products: A Detailed Analysis"

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Abstract

A Food and Drug Administration (FDA) drug evaluation procedure is given in this article, with particular attention to drugs and drug combinations that the agency has approved. This section covers the regulatory requirements of the federal FD&C Act as well as the interpretational guidelines pertaining to the New Drug Regulations (NDR). The functions, scientific and administrative frameworks, and recently established drug evaluation divisions of the Centre for Drug Evaluation and Research are explained. An outline of the research and development of new medications and anticicatories for plaque and gingivitis is provided. The new drug approval process consists of two phase, clinical trials and non-clinical studies of drug are completely ensure the safety of efficacy. In The United States drug and medical device are regulated or approved by different Division of US-FDA is assuring that food

[1]*and drug safety & effective. Following the evolution of the FD&C Act – the legal framework that guides the Food and Drug Administration 's evaluation of novel drugs is fascinating. The development and approval of drug products intended for human use were essentially unregulated in the US prior to 1906. The drug research process are involves safety of the product.This research contributes to the broader understanding of drug development and regulatory processes, aiming to enhance public health and well-being. The approval trends indicate a shift towards precision medicine and personalized therapies, reflecting advancements in biotechnology and genomics. FDA's drug evaluation procedure focusing on regulartory requirements established by the Federal Food, Drug and cosmetic (FD&C) Act and the interpretational guidelines outlined in the New Drug Regulations (NDR).*

Keywords : *FDA, approved drugs, combination drugs, disorders treatment, analgesic.*

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1. Introduction

In The United States drug and medical device are regulated or approved by different Division of US-FDA is assuring that food and drug safety & effective. Currently different countries have to follow different regulations requirements for approval of new drugs and approved combination drugs and also for the new drug evaluation process. The new drug approval process consists of two phase, clinical trials and non-clinical studies of drug are completely ensure the safety of efficacy.

FDA's New Drug Evaluation Process General Overview

Following the evolution of the FD&C Act - the legal framework that guides the Food and Drug Administration 's evaluation of novel drugs is fascinating. In 1906, the US virtually no regulations governing the approval of drugs intended for human use. The development and approval of drug products intended for human use were essentially unregulated in the US prior to 1906. [1]

- A regulation allowing the FDA to obtain pharmaceutical products from the market was passed in 1906, provided the agency could demonstrate the product had been modified with or mislabeled. A manufacturer of a new drug product was required by the New Drug Amendment of 1962 to demonstrate the product's safety and offer scientific evidence to support the claims made on the label.
- The FDA is required by the FD&C Act to enforce a NDRs, which are outlined in the Code of Federal Regulations. This concerns medications that have either been introduced into the US market after 1938 or whose labels have changed since 1938.
- Put another way, even though a drug product was already on the market before 1938, its labeling may have changed after 1938, making it qualify as a new drug product [1]. These modifications might include a revised dosage schedule, a new indication for use, or a change in the dosage form. Data on new drug applications could be compiled and examined. The FDA must review New Drug that can range from two months to seven years before a product is granted final marketing approval.

Types of phases for clinical trials are conducted for a new pharmaceutical product. The primary objective is safety

1. Phase 1: Clinical pharmacy research studies typically 1-10 male volunteers (MAXIMUM 50). primary purpose is efficacy
2. Phase 2: controlled studies in patients 50-200 patients with disease or conditions.
3. Phase 3: consists of both supervised and unsupervised trials with a maximum of 1,000 patients or more. Sponsors closely monitor the patients for adverse reactions and collect data for labeling and selective dosage requirements. Primary purpose is both safety and efficacy.

2. US FDA approved drugs from 2015-2020

- Anti-cancer drugs
- Drug for neurological disorders
- Drug for respiratory disorders

2.1 Anti-Cancer Drugs

The five most common cancer types as of 2018 were reported to be lung, colorectal, stomach, breast, and liver cancers by the World Health Organization (WHO) , which offers a thorough list of over 100 cancer types. 24 More than 9 million people died from cancer related causes in that year alone. [3]

The need for distinct diagnosis and treatment approaches for each type of cancer adds to the difficulty and burden of finding anticancer medications. A significant advancement in the creation of novel anticancer drugs was made in the 1940s with the discovery of antifolate drugs and nitrogen mustards as the first anticancer therapy. The FDA has approved 69 drug/drug combinations over the last five years to treat different types of cancer, including 51 small molecules and macromolecules. A kinase inhibitor called neratinib has been approved to treat HER2- overexpressed/amplified breast cancer. Acalabrutib, copanlisib and cobicistinib were the other anticancer kinase inhibitor medications that were approved. These drugs inhibited BTK, PI3K/AKT and MAPK, respectively.

2.2 Drug for Neurological Disorders

Neuropsychiatric disorders (schizophrenia, depression), neurodegenerative and neurotraumatic diseases (strokes, epilepsy) are the three categories of neurological disorders. Neural disorders are said to be responsible for 40.0% of worldwide 16.5% of deaths from causes other than cancer. In order to treat neurological disorders, the FDA approved 79 novel molecular entities until 2015. In short time ago, the Food and Drug Administration has accredited a total of twenty-three small molecules to treat neurological disorders: two oligonucleotides, four monoclonal antibodies, one cyclodextrin derivative, and one toxin. The chemical configurations of small molecules that have been authorised for use in the treatment of various neurological conditions.

2.3 Drug for Respiratory Disorders

COPD and interstitial lung disease are among the respiratory conditions that account for the third highest death rate globally 67. In short time ago the (FDA) has accredit just four drugs and three are asthma treatments known as monoclonal antibodies (mAbs) and one for COPD known as yupelri 86, a small molecule. The mAbs attach themselves to the TRF papilla a vital lymphokine that aids in the activation, ontogeny, and demarcation of acidophils. For inflammation associated with asthma, this procedure is crucial.

Reslizumab is approved for intravenous use; mepolizumab and benralizumab are approved for subcutaneous administration by the FDA. The inhalation dosage of long-acting Muscarinic Antagonist 86, a bronchodilator, is approved.

The Corona pandemic, which primarily affects the respiratory system, has led to a recent dramatic increase in research on medications for respiratory illnesses. By the end of 2020, it is anticipated that the global market for medications used to treat respiratory conditions will have grown from an estimated $65 billion in 2019. North America held 49% of the global market, with Far West coming in second with 19%. It is believed that Mylan, GSK, AstraZeneca, BoehringerIngelheim and other companies are the market leaders for respiratory medications.

3. A Survey of US Food and Drug Administration Approved Combination Drugs

3.1 Acetaminophen Combinations

COD combined with fioricet (acetaminophen, caffeine, butalbital Paracetamol has been used as an analgesic and feverish conditions. since it was first introduced in 1953. It is an ingredient in fifteen authorised combination drugs that are all prescribed to treat pain. Out of the authorised pairings, merely one comprises four elements, 40% feature three, and approximately half (53%) feature two. [2]

- Fioricet plus butalbital, acetaminophen, and caffeine for cod.

- Of the combinations, fifty-three percent have two components, forty percent have three, and only one combination with four components is allowed.

, and codeine).

The four combinations of caffeine, a stimulant found in natural products, increase the analgesic effects and absorption of Acetaminophen. Additionally, studies have demonstrated that the combination of aspirin, caffeine with acetaminophen is more effective and has a quicker action when treating migraines than ibuprofen. Tramadol and acetaminophen together have a quicker onset of action and a longer duration than either medication alone, which makes it an effective combination for managing postoperative pain.

One of the most harmful and contentious medications on the planet, acetaminophen was first created based on erroneous theories and assumptions. The maximum acetaminophen dosage as of 2011 is 325 mg.

The combination drugs. This is due to the fact that during metabolism, paracetamol changes into the extremely electrophilic species NAPQI. Toxicology is primarily caused by NAPQI, which can also damage the kidneys, interfere with foetal development, and result in acute liver failure.

3.2 Aspirin Combinations

Nonsteroidal anti-inflammatory drugs, or NSAIDs, like aspirin were first made available by Bayer in 1899. In 2021 Aspirin is recommended for use as an anti-inflammatory and pain reliever both on its own and in combination with other medications. But aspirin also acts as an antiplatelet, thinned blood platelet. When combined with other medications, it can be used to treat a variety of cardiovascular conditions.

Since the 1950s, aspirin combinations have been authorised continuously; four new combinations are accrediting every ten years.

Many drugs and stimulants, such as norotics or painkillers,analgesics (acetaminophen), vasodilators (diprodimole), proton pump inhibitors (omeprazole),antihistamines (orphenadrine), stimulants (caffeine), and myorelaxant of the carbamate class have been combined with aspirin at various times. Aspirin and oxycodone were combined to create the combination medication Percodan in 1950. Yosprala was the most recent aspirin combo accredit, and it was made available in 2016. In order to prevent cardiovascular events, patients who are susceptible to gastric ulcers caused by aspirin are prescribed Yosprala, a platelet aggregation inhibitor.

3.3 Ethinyl Estradiol Combinations

The sale of contraceptive pills began more than 50 years ago.CarlDjerassic create the first oral contraceptive, norethindrone, in the early 1950s. It was a progestin. Lessthan ten

years later, the FDA approved Enovid (lnorethynodrel + mestanol), the firstcombination pill for contraception. Since its initial approval in 1943, ethyl estradiolhas been used in 15 combinations, 11 of which have a unique structural makeup.These all fall under the categories of endocrine, urogenital system and gonadocosticoids diseases. Ethyl estradiol is one oral contraceptive that is used to reduce the number of births. The merely accredit mixture of progynonl and beyond two compact speck cinstituent is Beyaz (ethinyl estradiol + diprose + levomelate). The term "oral contraceptives" was used to market these mixtures. The first estrogen medications combination to receive FDA approval was demulen (ethinyl estradiol plus ethynodioldiacetate), which was approved in 1970. The most recent estrogen medications combination to be approved was Xulane (ethinyl estradiol + norelgestromin) in 2014.

3.4 Amlodipine Combination

Amlodipine is a Dihydropyridine calcium channel blocker, which is long-acting and belongs to the third generation. It was first approved in 1981 to treat angina and hypertension. Additionally, ACE inhibitors (benazepril and perindopril), renin inhibitors (aliskiren), diuretics. (hydrochlorothiazide), and angiotensin-Il receptor antagonists (telmisartan, valsartan, and Olmesartan) are used in combination with amlodipine.

Lotrel, the first medication containing amlodipine, was approved in 1995. Benzapril and amlodipine are combined in lotrel. The most recent year that amplodipine combinations were approved was Tribenzor (olmesartanmedoxomil+hydrochlorothiazide+amlodipine), Amturnide(aliskiren+hydrochlorothiazie + amlodipine), and Tekamlo (aliskiren + amlodipine).

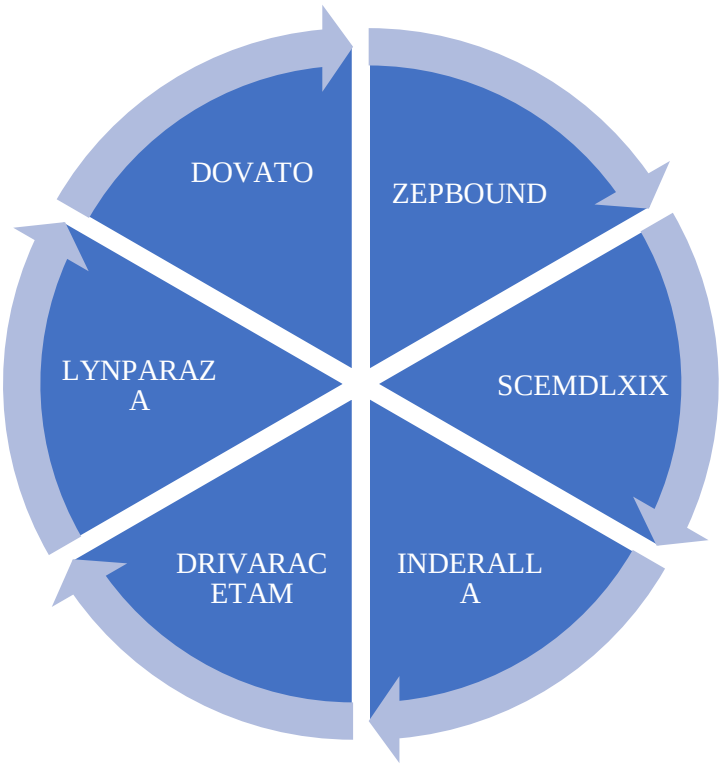

Figure 1. USFDA approved drugs in 2023

4. US FDA approved oncology drugs

4.1 Melanoma

In the US, 2015 is expected to bring 9940 deaths and 73,870 new cases of melanoma diagnosis. Sixty-two is the average life at interpretation. The average endurance for progressive illness is only 6–9 months, and the 5-year endurance value is below 5%. Several deputy pillager increases response rates in comparison to sole deputy pillager , but it has little to no OS benefit. Ipilimumab (2011) and trametinib (2013) were the accredit to treatments for melanoma. [5]

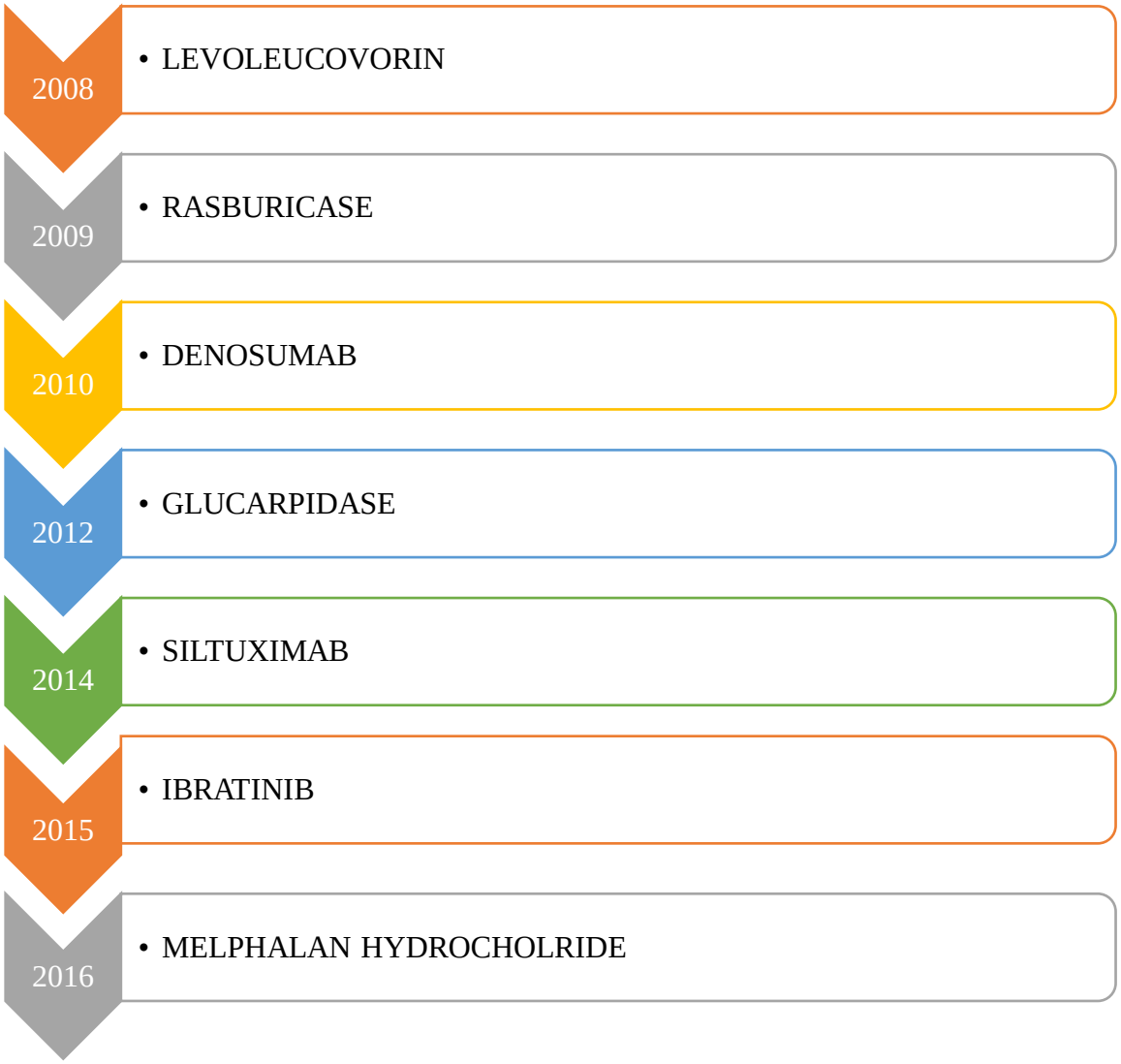

Figure 2. US FDA Approved Drugs 2018 – 2023

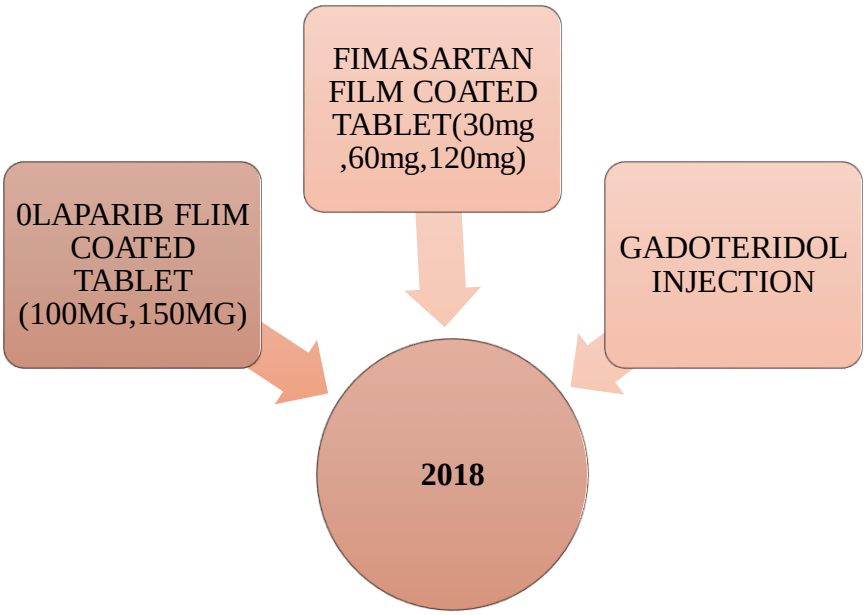

Figure 3. US FDA Approved Drugs 2018

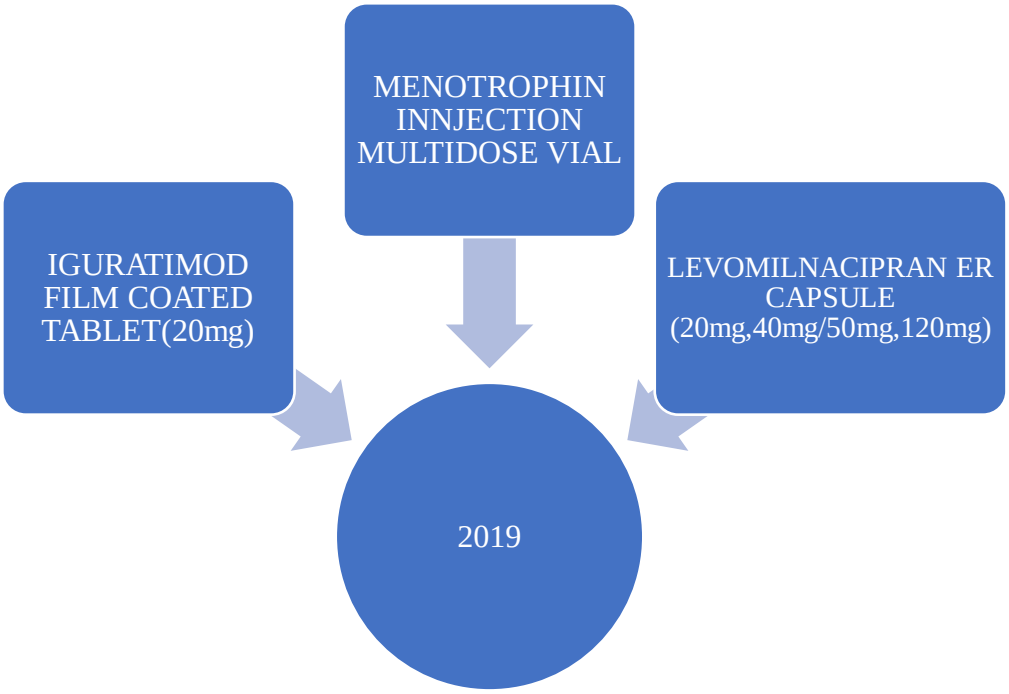

Figure 4. US FDA Approved Drugs 2019

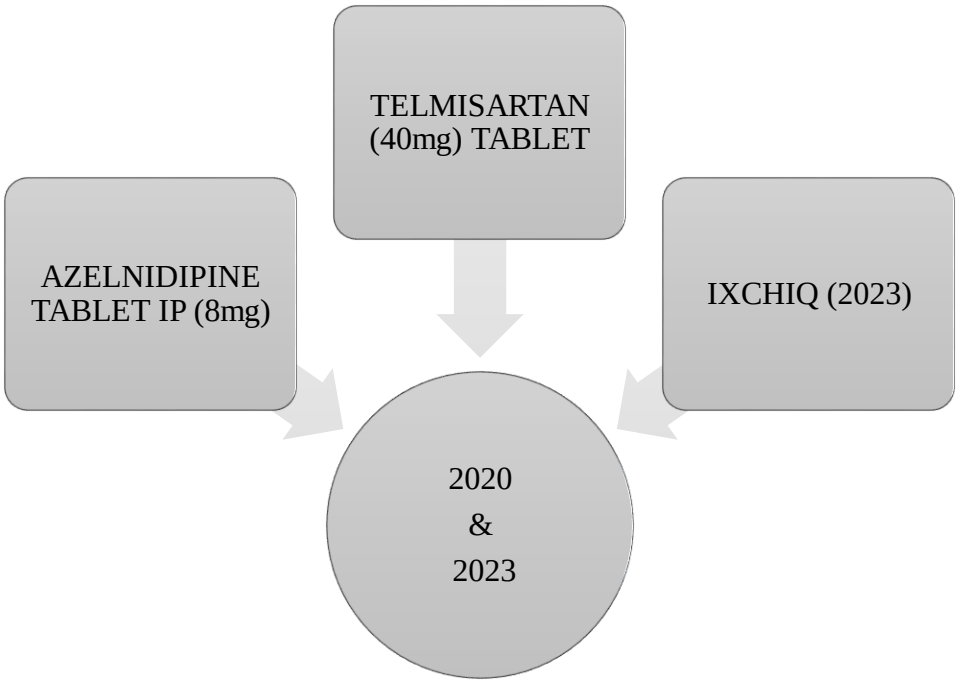

FIGURE 5. US FDA Approved Drugs 2018 – 2023

5. Conclusion

Our study provides valuable insights into the landscape of USFDA approved drugs, highlighting trends and characteristics of new drug approvals. The findings underscore the importance of continued research and development efforts in addressing unmet medical needs and improving patient outcomes. Analyzing approval trends, therapeutic areas, and emerging innovations reveals the dynamic nature of drug development, crucial for researchers, healthcare professionals, and policymakersThe survey of USFDA approved drugs is essential for understanding the evolving pharmaceutical landscape and making informed decisions for public health. It is evident that the pharmaceutical industry is continuously innovating to meet the healthcare needs of the population. The approval trends indicate a shift towards precision medicine and personalized therapies, reflecting advancements in biotechnology and genomics.While the USFDA approval process is rigorous, further research is needed to explore the long-term impacts of these approvals and the factors influencing the drug approval process. This research contributes to the broader understanding of drug development and regulatory processes, aiming to enhance public health and well-being."

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