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REVIEW ARTICLE **OPEN ACCESS**

Trend Analysis of Anti-Viral Drugs Approved by USFDA During 2019-2023

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ABSTRACT
Both the treatment of patients and pharmaceutical research and development depend on the identification of innovative medications. A viable approach to achieving this crucial objective is the repurposing of current medications that can have expected side effects. Thorough examination and systematic research of licensed medications may yield insightful information about patterns in the development and may help methodically with the ongoing development of novel medications. Drug Evaluation and Research Centre of the Food and Drug Administration (FDA) Novel medications, some of which are really unique and aid in the advancement of clinical treatment, are summarized annually by Research (CDER). As such, an analysis of drug approval trends by the FDA during the last 5 decades was carried out. From 2019-2023 we just collected the how many new drugs are formed and in that how many are the anti-viral drugs I just given the graphs and also collected the for what reason the drugs are rejected finally given the conclusion
Keywords: *Antiviral drugs, USFDA, Viral infection, Drug development*

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INTRODUCTION

The Food and Drug Administration (FDA) has overseen promoting safe and efficient medications since its founding in 1930. Following 1962 Changes to the federal Food New medications were evaluated for safety and efficacy using well-controlled trials, which established the standard of evidence under the Drug and Cosmetic Act (FD and C). [1-2,3] In 1906, Congress enacted the first federal drug legislation, outlawing the sale of contaminated or mislabelled medications in addition to food and beverages. The federal law that assures a medicine is safe before being on sale was then approved by Congress in 1938 [1]. (Source:) Following the 1962 Kefauver-Harris Drug Amendment, not only safety. The Orphan Drug Act of 1983, which promotes the discovery of medications for uncommon disorders, was another significant turning point. [1] This statute also provides tax rebates and other financial incentives for seven years of exclusive commercial rights for clinical research. Get in to generic prescribing emerged as a crucial area to reduce the average person's expense. Act of 1984 (Hatch-Waxman Act) promotes generic drug manufacture while defending brand rights identify the producers.[2] The creation of Clinical Trials.gov in 1999 aimed to provide patients with information about current clinical research addressing continuing, promising treatments.[2] In 2004, the article "Innovation or Stuckness: Obstacles and Opportunities on the Crucial Route to Novel Medical Products" was published by the FDA, emphasizing group efforts. required to revolutionize the assessment, development, and production of health care items. [1,2,3] Ever thereafter, persistent reformations have been added with consideration for patient safety and needs. We want to examine the patterns in the FDA's approval of innovative drugs during the last five years and assess the reasons behind them, given the recent quick pace of medication approvals. Additionally, primary care physicians would be well to become knowledgeable about these innovative agents, since they are being prescribed and adopted by major thought leaders.

Drug Development process:

Step 1 shows that laboratory research on a novel medication is underway. In the second phase, drugs are tested in labs and on animals to provide basic safety information. Step 3: Drugs are tested on humans to ensure their efficacy and safety. Step 4: FDA review teams carefully go over all of the provided information

on the medicine or device and decide whether or not to approve it. Step 5: Once the product is ready for public use, the FDA keeps an eye on all drug and device safety.

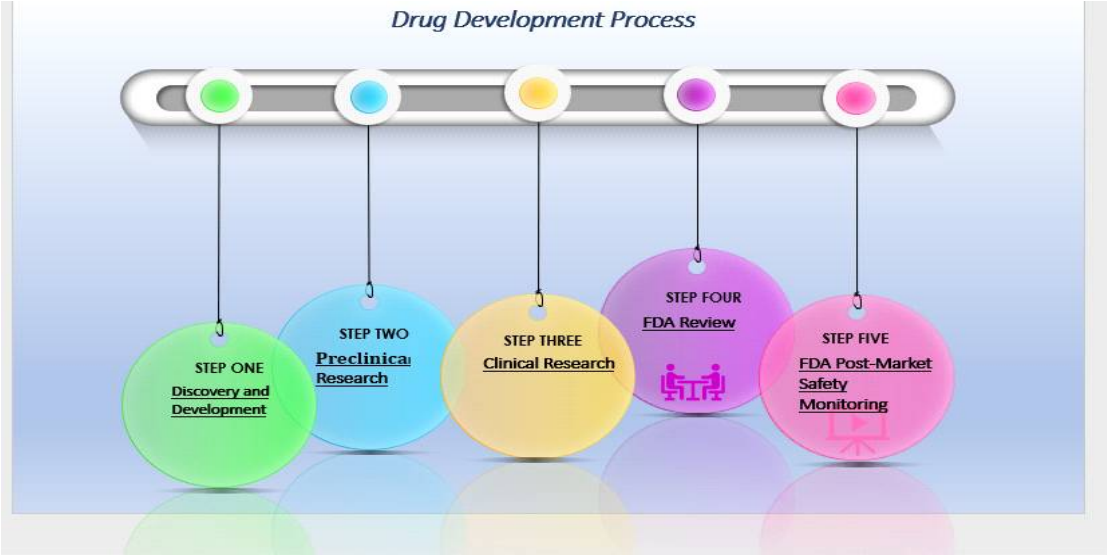

Figure-1 It shows about how the drug development process [4]

New Drug approval process as per USFDA: [5]

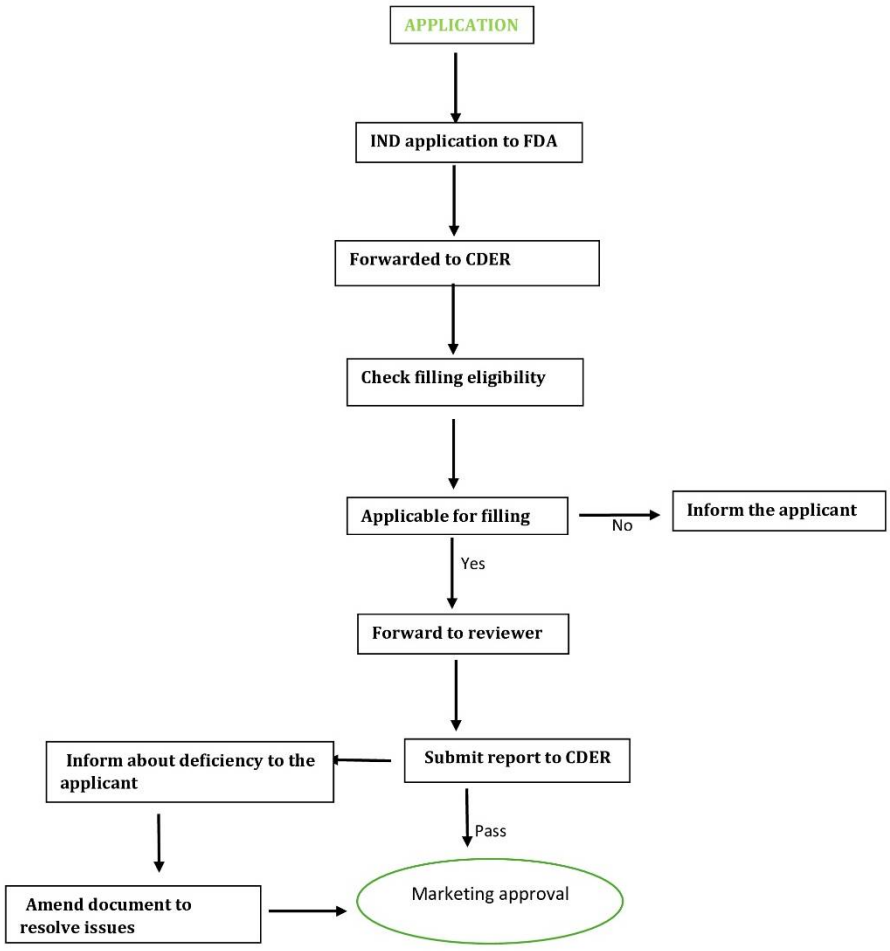

Figure-2 New Drug approval process as per USFDA: [5]

Drug Approval and Safety: Before novel medications and treatments are made available to the general public, the USFDA evaluates and approves them. This entails conducting thorough clinical trials to assess the goods' effectiveness and safety. scientific investigation. The organization further oversees medication safety and responds to reports of any negative consequences following approval [6]

Steps of viral infections

The process of viral infection entails the introduction of viral DNA into the host cell, its replication, and the release of fresh viruses. The viral replication process in six phases comprise the adhesion, invasion, uncoating, replication, assembly, and release of viruses. The virus's steps life cycle, emphasizing the entrance and departure of the viruses are detailed here.

During the attachment and penetration stage, the virus binds to a host cell and injects its genetic material into the cell. The following phase involves the integration of the viral DNA or RNA into the host cell's genetic material, which causes the host cell to duplicate the viral genome. In this stage of the virus life cycle, uncoating, replication, and assembly take place.

The host cell releases the newly formed viruses by burst cells, waiting for the cell to die, or budding off through the cell membrane. [7,8]

MATERIAL AND METHODS

The FDA's online database was used to gather data for the study under the heading of innovative medicine approvals, covering the period from 2019 to 2023. An annual report from CDER includes a list of all new medications that were authorized in a certain year. Moreover, any fresh proof it is mentioned that a medication has already received FDA approval. Every medication included in the drug overview for that particular year were divided based on criteria: Count of medicines that have been authorized annually, medication class in pharmaceuticals, use indication in patient demographic, the kind of permission obtained, and/or both quicker approvals. Additionally, an electronic database literature search was done. such as Cochrane, Google Scholar, clinicaltrials.gov, and PubMed database to verify the information that helped medications be approved.

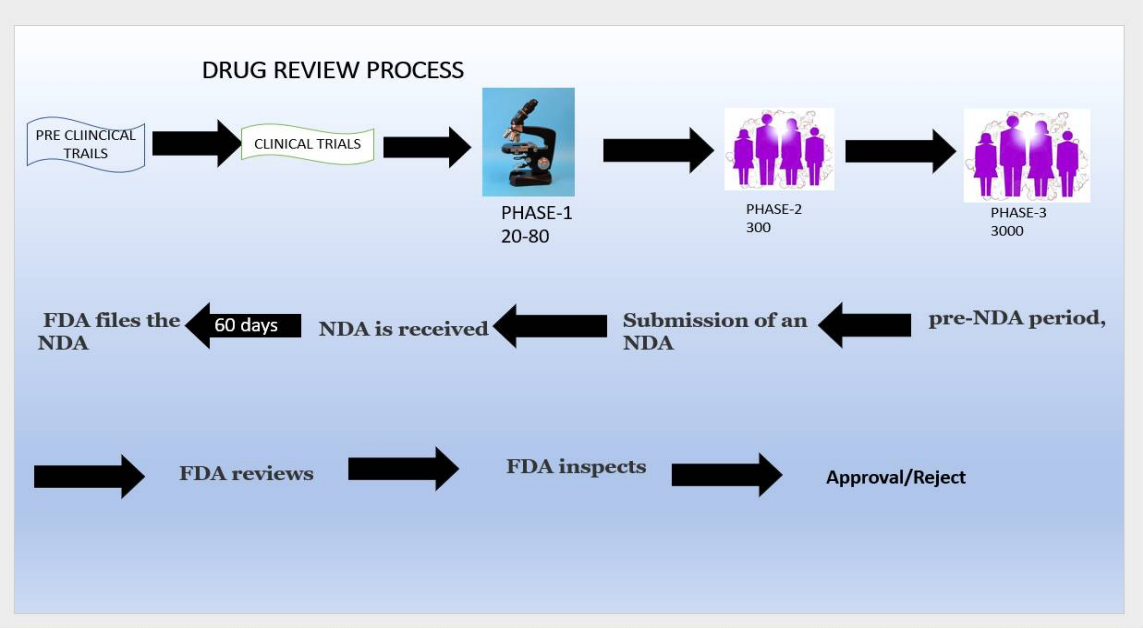

Figure-3 It shows about how the drug review process [9]

RESULTS

Trends in drug approval in the last 5 years as follows

2019-2023: Only 24 of the 216 new medications that have been authorized in the previous five years are biologics. These findings show that fewer investigational new drug applications (INDAs) for the antibiotic and antiviral categories are being submitted. The pharmaceutical industry's research and development efforts may be directed towards other therapeutic categories, or it might be the result of a New Chemical Entity (NCE) failing during the development phase. The following table lists antivirals from 2019 to 2023

Table-1 This shows the list of the anti-viral drugs approved by the USFDA from last 5 years from 2019 to 2023 [10,11,12,13,14]

Graphs

The graphs that indicates that the year wise how many drugs are approved in that out of that how many are anti-viral drugs are mentioned below

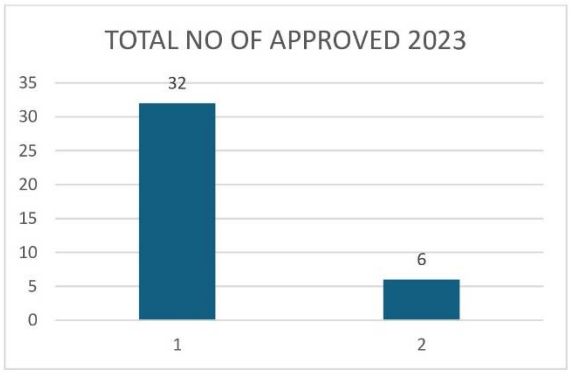

Figure-4 Total no of approved drugs in 2023

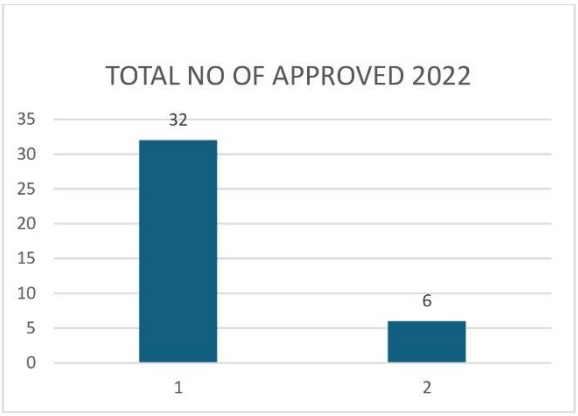

Figure-5 Total number of approved drugs in 2022

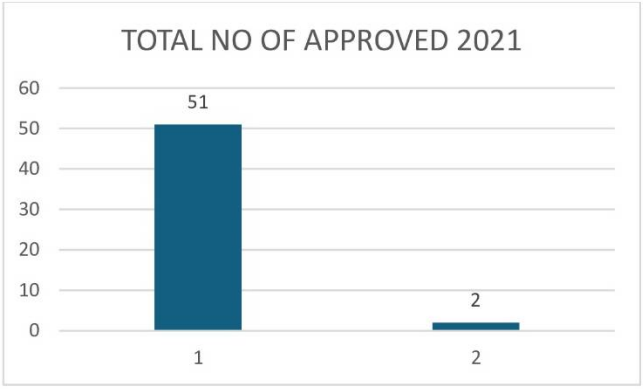

Figure-6 Total number of approved drugs in 2021

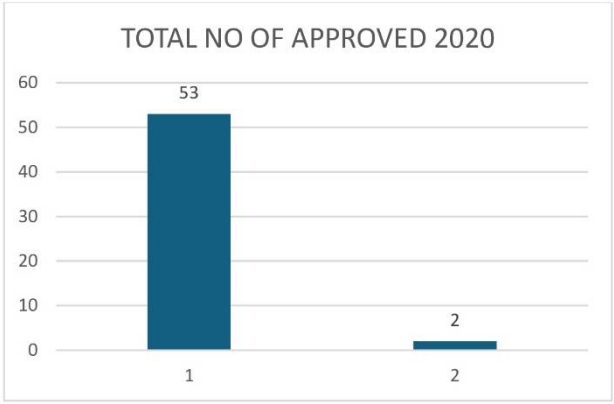

Figure-7 Total number of approved drugs in 2020

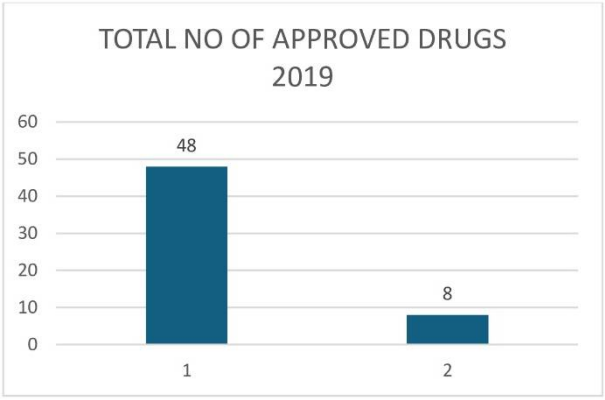

Figure-8 Total number of approved drugs in 2019

In the below graph you can see that growth of the anti-viral drugs from last 5 years from 2019-2023
In the 2019 the anti-viral drugs are approved more compared to the remaining 4 years

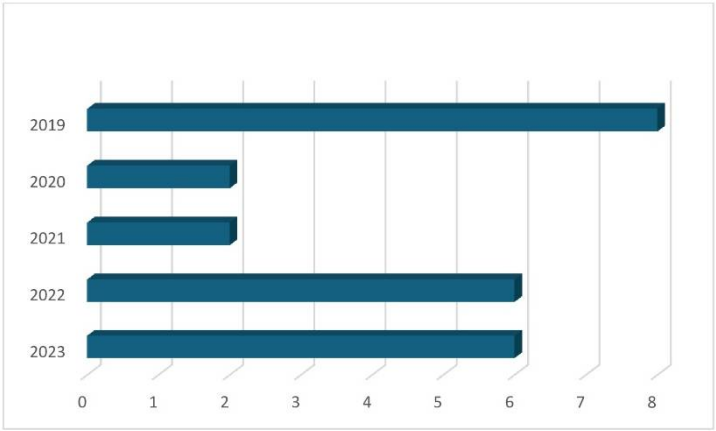

Figure-9 Total number of approved drugs from 2019-2023

DISCUSSION

The pharmaceutical sector and CDER collaborate to innovate medication discovery and development. To begin with The FDA offers comprehensive assistance through CDER, including everything from the testing and manufacturing procedure to the comprehension of the science underlying the condition.

When it comes to introducing innovation into the drug development process and approving novel medications and biological products, CDER is essential. These comprise both novel classes of medications and those in the same class with minor structural modifications. It is quite difficult to get FDA clearance for a new medicine. The rate of medicine approval has increased significantly from prior years. We have noticed that, generally speaking, illness patterns and medical demands do not change significantly, Unmet

medical requirements and information from fundamental research are expected to fuel the pharmaceutical industry. Act of Right to Try

Since we haven't made any advances, India will eventually follow the US Food and Drug Administration's (USFDA) practice of approving drugs. But still, Taking into account the prevalence of sickness in our country, which mostly includes infectious illnesses such as malaria and TB In addition to cancer, diabetes, and hypertension, new drugs are per year from the USFDA do not meet the unmet need inside our nation

In addition to receiving education from their colleagues, primary care physicians have been known to prescribe several innovative medications in the past, such as dabigatran, sitagliptin, and aliskiren. [16] These days, following an autoimmune and cancer diagnosis illnesses that many individuals see primary care facilities for further treatments or infusions. Thus, it is essential that doctors working in primary care settings to stay current on new medication approvals as well as novel uses for already authorized medications

Reasons for Rejected Drugs from 2019-2023[17]

Medolife Rx: Articles recognized in the official Homeopathic Pharmacopeia of the United States (HPUS) or any supplement to it are considered "drugs" under section 201(g)(1) of the FD&C Act, 21 U.S.C. 321(g)(1). The same legal requirements apply to homeopathic medication products as they do to conventional drugs; the FD&C Act does not exclude homeopathic drugs from adulteration, misbranding, or FDA clearance requirements.

Noble Elements, LLC: According to sections 301(d) and 505(a) of the Act, 21 U.S.C. 355(a), new medications may not be lawfully introduced or conveyed for introduction into interstate commerce without prior permission from FDA, with several exceptions that do not apply here. A new medicine gets approved by the FDA based on facts and data from scientific studies that show the drug is both safe and effective.

Purecraft LLC: Our assessment indicates that these goods are unapproved novel medications that are being supplied in violation of 21 U.S.C. § 355(a), section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). In addition, these goods violate section 502 of the FD&C Act, 21 U.S.C. § 352, regarding misbranded pharmaceuticals. The introduction, or the manner in which things are introduced goods into interstate commerce is forbidden under the Federal Deposit and Certificate Act's sections 301(a) and (d), 21 U.S.C. § 331(a) and (d).

In The year of 2022

Iodine Products Inc: We have reviewed these goods and found that they are unapproved new medications distributed in violation of 21 U.S.C. § 355(a), section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). In addition, according to section 502 of the FD&C Act, 21 U.S.C. § 352, these goods are misbranded pharmaceuticals. According to sections 301(a) and (d) of the FD&C Act, 21 U.S.C. § 331(a) and (d), it is illegal to introduce certain items into interstate commerce or to supply them for introduction.

Viraldine, LLC: Our assessment indicates that these goods are unapproved novel medications that are being distributed in violation of 21 U.S.C. 355(a), section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Moreover, these goods violate 21 U.S.C. 352(ee), section 502(ee) of the FD&C Act, as misbranded pharmaceuticals. Sections 301(a) and (d) of the FD&C Act, 21 U.S.C. 331(a) and (d), prohibit the introduction of these items into interstate commerce, or the delivery of products for introduction. Below is a more detailed description of these infractions.

In the Year 2021

Kaleido Biosciences, Inc: Kaleido said in its response to the Form FDA 483 that it is creating a process to decide (in consultation with FDA) whether an IND is required when creating protocols for clinical studies in a population of patients where endpoints could be interpreted as identifying, reducing, treating, preventing, or curing a disease. There are insufficient specifics in Kaleido's corrective action plan regarding their new IND determination method. We are unable to assess if Kaleido's corrective action plan is sufficient to stop such breaches in the future in the absence of these facts. [18]

In the Year Of 2020

Riverstone LLCMARCS, MARCS-CMS 611759, MARCS-CMS 611790, CMS 607751, MARCS-CMS 607149

The Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. § 355(a), section 505(a) prohibits the sale of unapproved new pharmaceuticals, and the FDA has concluded that the drugs listed above are the same basis for rejection. In addition, according to section 502 of the FD&C Act, 21 U.S.C. § 352, these goods are misbranded pharmaceuticals. According to sections 301(a) and (d) of the FD&C Act, 21 U.S.C. § 331(a) and (d), it is illegal to introduce certain items into interstate commerce or to supply them for introduction. [19]

In the Year Of 2019

Sovereign Laboratories, LLCMARCS: llcmarcson the other hand, a product that is "intended for ingestion" is what the act defines as a "dietary supplement" in section 201(ff)(2)(a)(i) [21 u.s.c. §

321(ff)(2)(a)(i)]. oral spray products are neither foods or dietary supplements because their intended route of entry into the body is through the mucosal tissues at the back of the throat**. [20]**
BGP, LLC OCLO LLC/OCLO Nanotechnology Science, Halodine, LLC
By above mentioned drugs are the same reason for rejecting
RE: Unapproved Novel Drug Products Associated with COVID-19 Coronavirus Disease Our assessment indicates that these goods are unapproved novel medications that are being distributed in violation of 21 U.S.C. 355(a), section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Furthermore, according to sections 502(a) and (ee) of the FD&C Act, 21 U.S.C. 352(a) and (ee), these items are misbranded pharmaceuticals. Sections 301(a) and (d) of the FD&C Act, 21 U.S.C. 331(a) and (d), prohibit the introduction of these items into interstate commerce, or the delivery of products for introduction. Below is a more detailed description of these infractions. [21]

Year	Dug name	Mode of use
2023	Paxlovid	To treat mild-to-moderate COVID-19 in adults at high risk for progression to severe COVID-19
2023	Elecsys HIV Duo	Elecsys HIV Duo
2023	Arexvy	lower respiratory tract disease
	ABRYSVO	Indicated for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older.
2022	Spikevax	For covid-19 treatment
2022	Sunlenca	To treat adults with HIV whose HIV infections cannot be successfully treated with other available treatments due to resistance, intolerance, or safety considerations
2022	Cabotegravir	short-term prevention of human immunodeficiency virus type 1 (HIV-1) infection
2022	Cabotegravir / Rilpivirine	Treatment of human immunodeficiency virus type 1 (HIV-1) infection in certain adults and children 12 years of age
2022	Alinity HYPERLINK "https://www.fda.gov/vaccines-blood-biologics/alinity-s-anti-hcv-ii-assay" s Anti-HCV II Reagent Kit	Intended to screen individual human donors, including volunteer donors of whole blood and blood components, and other living donors for the presence of anti- HCV.
2022	Measles, Mumps and Rubella Vaccine,	Indicated for active immunization for the prevention of measles, mumps, and rubella in individuals 12 months of age and older.
2022	Measeles mumps and rubella vaccine	indicated for active immunization for the prevention of measles mumps and rubella in individuals 12 months age of and older
2021	Prehevbrio	Indicated for prevention of infection caused by all known subtypes of hepatitis B virus in adults 18 years and older.
2021	Comirnaty	For covid-19 treatment
2020	Fostemsavir	Hiv infection
2020	AUDENZ	Indicated for active immunization for the prevention of disease caused by the influenza A virus H5N1 subtype contained in the vaccine.
2019	Dolutegravir / Lamivudine	HIV-1 Infection in Adults with No Antiretroviral
2019	ERVEBO	ERVEBO® is a vaccine indicated for the prevention of disease caused by Zaire ebolavirus in individuals 18 years of age and older.
2019	JYNNEOS	For prevention of smallpox and monkeypox disease in adults 18 years of age and older determined to be at high risk for smallpox or monkeypox infection.
2019	Geenius HYPERLINK "https://public4.pagefreezer.com/content/FDA/29-01-2023T09:49/https:/www.fda.gov/vaccines-	Human Immunodeficiency Virus Types 1 and 2 (Recombinant and Synthetic Peptides)

	blood-biologics/geenius-hiv-12-supplemental-assay-bl-125670" HIV 1/2 Supplementary Assay	
2019	Alinity HYPERLINK "https://public4.pagefreezer.com/content/FDA/29-01-2023T09:49/https:/www.fda.gov/vaccines-blood-biologics/alinity-s-anti-hbc" s Anti-HYPERLINK "https://public4.pagefreezer.com/content/FDA/29-01-2023T09:49/https:/www.fda.gov/vaccines-blood-biologics/alinity-s-anti-hbc"HBc HYPERLINK "https://public4.pagefreezer.com/content/FDA/29-01-2023T09:49/https:/www.fda.gov/vaccines-blood-biologics/alinity-s-anti-hbc" assay	The Alinity s Anti-HBc assay is intended to screen individual human donors, including volunteer donors of whole blood and blood components, and other living donors for the presence of anti-HBc. The assay is also intended for use in testing serum and plasma specimens to screen organ donors when specimens are obtained while the donor's heart is still beating, and in testing serum specimens to screen cadaveric (non-heart-beating) donors.
2019	Alinity HYPERLINK "https://public4.pagefreezer.com/content/FDA/29-01-2023T09:49/https:/www.fda.gov/vaccines-blood-biologics/approved-blood-products/alinity-s-hiv-agab-combo-assay" s HIV Ag/Ab Combo assay	The Alinity s HIV Ag/Ab Combo assay is intended to screen individual human donors, including volunteer donors of whole blood and blood components, and other living donors for the presence of anti-HIV-1/HIV-2 and HIV-1 p24 antigen.
2019	Alinity s Anti-HCV	The Alinity s Anti-HCV assay is a chemiluminescent microparticle immunoassay (CMIA) used for the qualitative detection of antibodies to hepatitis C virus (HCV) in human serum and plasma specimens on the Alinity s System.
2019	DENGVAXIA	Dengue Tetravalent Vaccine, Live is indicated for the prevention of dengue disease caused by dengue virus serotypes 1, 2, 3 and 4. Dengue Tetravalent Vaccine, Live is approved for use in individuals 9 through 16 years of age with laboratory-confirmed previous dengue infection and living in endemic areas.

Table-1 This shows the list of the anti viral drugs approved by the USFDA from last 5 years from 2019 to 2023 [8,9,10,11,12]

CONCLUSION

In conclusion, our examination of the patterns in the USFDA's approvals of antiviral drugs between 2019 and 2023 offers important new perspectives on the state of pharmaceutical innovation and regulatory policy. The statistics and graphs included in this study show that the pharmaceutical industry has seen a noticeable increase in the approval of antiviral medications throughout this time. [19] The FDA's description of the drug development process includes thorough examination and monitoring at different phases to guarantee the security and effectiveness of new drugs before they are released into the market. The business is focusing on treating viral infections, which may be impacted by pandemics and newly developing infectious illnesses, as seen by the patterns in medication approvals. The reasons why some medications were rejected within that time frame are also clarified by our investigation. FDA standards must be followed to the letter, and unapproved new pharmaceuticals risk regulatory action. The significance of upholding safety and effectiveness criteria in pharmaceutical development is highlighted by comprehending the rationale for rejections. It is imperative that medical practitioners, particularly primary care physicians, remain up to date on recently authorized pharmaceuticals in the future. In order to offer the best possible care for patients, healthcare professionals must be informed about the constantly changing pharmaceutical industry. Collaboration between pharmaceutical businesses and regulatory agencies such as the FDA is essential to fostering innovation in the pharmaceutical sector as it continues to change. The knowledge gleaned from this approach advances our collective comprehension of developments in medication development and stress the value of continuous research and development in tackling issues related to public health.

Ethics approval and consent to participate: Not Applicable

AUTHOR CONTRIBUTIONS

Gopi Chand Raguri is the main contributor of the manuscript, writing and editing, and collecting data editing, and submission/correspondence of the above review article. The project was conducted under the supervision of: Koushik Yetukuri, Associate Professor.

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