U.S. Food and Drug Administration (FDA)

Analysis of FDA Using SQL & Power BI

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Project Objective

The U.S. Food and Drug Administration (FDA) is a federal agency responsible for protecting public health by regulating food safety, pharmaceuticals, medical devices, cosmetics, and more. It evaluates the safety and efficacy of drugs and products, enforces regulations, and responds to emerging health risks. iVision is collaborating with the FDA to analyze their dataset. As an iVision analyst, your task is to create informative reports by thoroughly analyzing this data using tools like MySQL and Power BI.

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Analysis By SQL/Power BI

1.1 Approved Drugs Yearly Trends

1. 2002 Peak:

- **2002 saw the highest drug approvals at 5,661**, a major outlier, possibly driven by favorable regulations or increased R&D efforts.

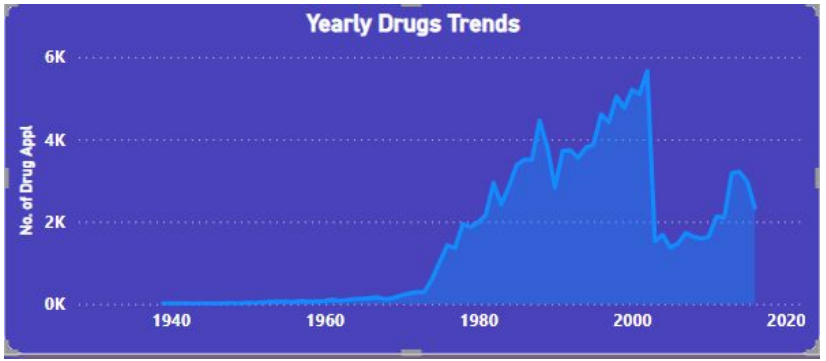
2. Post-2002 Fluctuations:

- **Decline After 2002**: Drug approvals dropped sharply in the years following 2002.
- **Fluctuations**: From 2012 to 2016, approvals fluctuated between 2,095 and 3,212 drugs, showing no consistent growth or decline.
- **2014 Recovery**: A peak in 2014 saw 3,212 approvals, followed by another dip.

3. Key Observations:

- **2002 remains an outlier**, with no other year approaching its numbers.
- **Yearly Fluctuations** indicate external factors, such as regulatory shifts or market conditions, impacting approval rates.

Year	Approved
2016	2339
2015	2971
2014	3212
2013	3171
2012	2095
2011	2125



1.2 Top 3 & Least 3 Drugs

Top 3 Years with the Highest Drug Approvals:

1. **2002**: 5,661 drugs approved
2. **2000**: 5,204 drugs approved
3. **2001**: 5,098 drugs approved

Top 3 Years with the Least Drug Approvals:

1. **1945**: 5 drugs approved
2. **1943**: 6 drugs approved
3. **1944**: 9 drugs approved

Drugs Approved Year	No. of Drugs Approved
2002	5661
2000	5204
2001	5098

Drugs Approved Year	No. of Drugs Approved
1945	5
NULL	5
1943	6
1944	9

1.3 Yearly Approval trends wrt Sponsors

1. **Early Activity**: In the 1930s and 1940s, companies like **Organon USA Inc.** and **Merck Sharp & Dohme** were key players, though overall drug approvals were lower.
2. **Sponsor Dominance**: **Merck Sharp & Dohme** consistently leads in drug approvals, indicating a steady flow of innovations.
3. **Yearly Fluctuations**: Drug approvals vary significantly by year, influenced by regulatory changes, sponsor activity, and market demand.
4. **Recent Trends**: Large pharma companies continue to dominate, but smaller companies are increasingly contributing to approval spikes.
5. **Overall Trend**: The drug approval trends showcase how market leaders, like **Merck Sharp & Dohme**, maintain a dominant position, while other companies see periodic spikes based on their R&D cycles or specific innovations.

Drugs_Approved_Year	SponsorApplicant	Approved_Drugs_Count
1939	ORGANON USA INC	13
1939	LILLY	4
1939	MEDA PHARMS	4
1939	MERCK SHARP DOHME	1
1940	GD SEARLE LLC	2
1940	ISO TEX	1
1940	POYTHRESS	1
1941	LEDERLE	2
1941	US PHARM HOLDINGS	1
1941	LILLY	1
1942	US PHARM HOLDINGS	7
1942	WYETH PHARMS INC	6
1942	HOSPIRA	4
1942	PHARMACIA AND UPJ...	3
1943	RECORDATI RARE	4

1.4 Yearly Approval trends wrt Sponsors

- **Top Sponsors**: Sponsors like **Lilly**, **Organon USA Inc.**, and **ISO Tex** have the highest rank with multiple approvals, indicating strong activity during this period.

- **Tie in Approvals**: Several sponsors, such as **Lilly** and **Organon USA Inc.**, share the same number of total approvals, resulting in a shared rank, indicating competitive performance among the top sponsors.

- **Lower Ranked Sponsors**: Companies like **Meda Pharms** and **Merck Sharp Dohme** have fewer approvals and rank lower compared to the top-performing sponsors, showing less activity or presence during the observed period.

- **Ranking Variability**: The sponsor ranks fluctuate based on minor differences in total approvals, suggesting a highly competitive environment with small differences between companies.

SponsorApplicant	Total No. Of Approval	Sponsor Rank wrt Approval
LILLY	2	1
ORGANON USA INC	2	1
MEDA PHARMS	1	3
MERCK SHARP DOHME	1	3
ISO TEX	1	1
GD SEARLE LLC	1	1
POYTHRESS	1	1
US PHARM HOLDINGS	1	1
LEDERLE	1	1
LILLY	1	1
PHARMACIA AND UPJ...	1	1
WYETH PHARMS INC	1	1
US PHARM HOLDINGS	1	1
HOSPIRA	1	1

2.1 Group products based on Marketing Status

- **Most Common Status (1)**: The majority of products (18,344) fall under **ProductMktStatus 1**, making it the dominant status.
- **Second Common Status (3)**: **14,209 products** are associated with **ProductMktStatus 3**, representing a significant portion.
- **Less Common Statuses (4 and 2)**: **ProductMktStatus 4** and **2** have much fewer products, with **1,231** and **681** respectively.
- **Skewed Distribution**: The data is heavily skewed towards **ProductMktStatus 1** and **3**, with fewer products in the other categories.

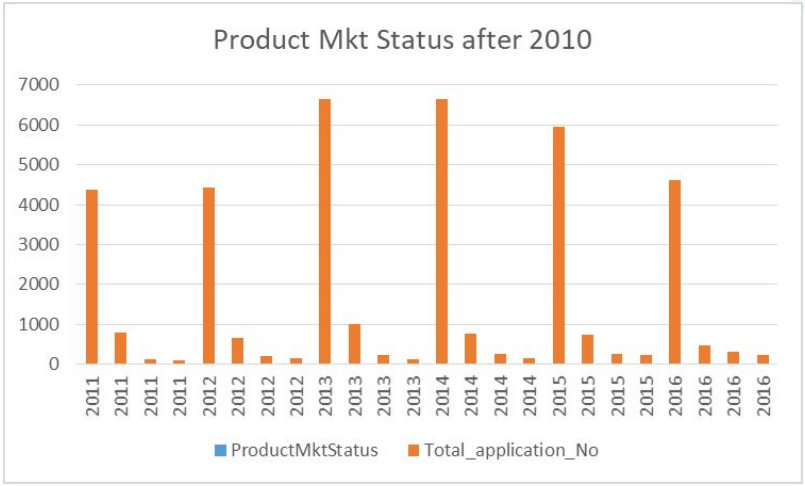
	ProductMktStatus	Product_Count
▶	1	18344
	3	14209
	4	1231
	2	681

	drugname	ProductMktStatus
▶	PAREDRINE	3
	SULFAPYRIDINE	3
	LIQUAEMIN SODIUM	3
	LIQUAEMIN LOCK FLUSH	3
	HEPARIN SODIUM	3
	LIQUAEMIN SODIUM PRESERVATIVE FREE	3
	HISTAMINE PHOSPHATE	3
	BUTISOL SODIUM	3
	BUTISOL SODIUM	1

Note that: 1: Marketed
2: Withdrawn
3: Pending
4: Pre-marketed

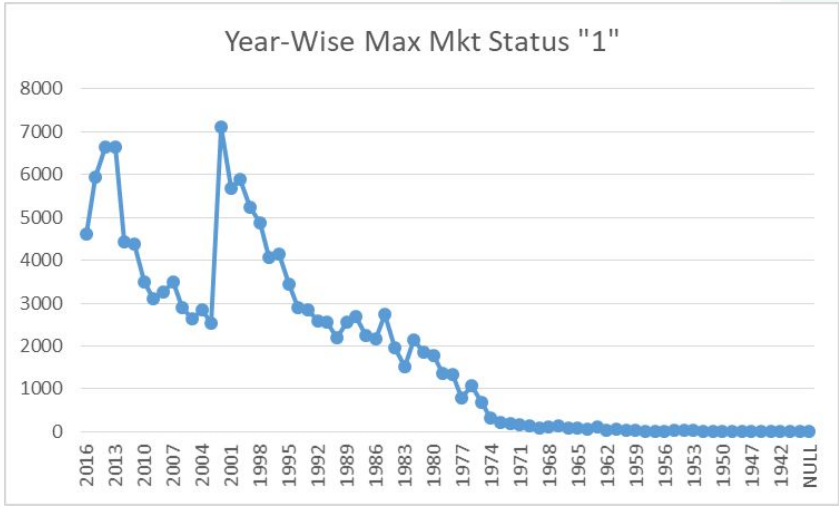
2.2 Applications by MarketingStatus (Post-2010)

- **ProductMktStatus 1 Dominance**: Status 1 consistently leads with the highest applications, peaking in 2013 (6,654) and 2014 (6,637).
- **Steady Status 3 Activity**: Status 3 remains steady, with the highest in 2013 (1,009 applications).
- **Lower Activity in Status 2 and 4**: These statuses have fewer applications, peaking at 253 and 292, respectively.
- **Peak Years**: 2013 and 2014 show the highest activity, especially for Status 1, suggesting market or regulatory factors.



2.3 Applications by MarketingStatus (Post-2010)

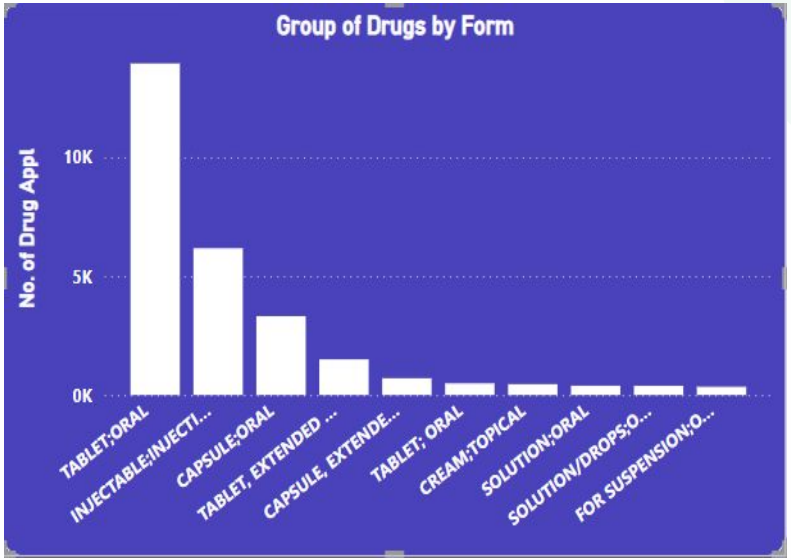
- **ProductMktStatus 1 Dominance**: The majority of products (18,344) fall under **ProductMktStatus 1**, making it the dominant status.
- **Peak in 2001**: Highest activity with nearly 7,000 applications.
- **Decline after 2004**: Steady drop in applications post-2004.
- **Stable from 2010-2016**: Consistent levels around 5,000–6,000 applications.
- **Long-Term Decline**: Gradual decrease since 1990, with minimal early activity.
- **Minimal Activity in Early Years**: Prior to 1990, activity levels were significantly lower, with minimal applications for Status 1, showing that this status became more prominent in later years.



3.1 Categorize Products by dosage form

- **Oral Products Lead**: Tablets dominate with **13,942 products**, followed by capsules and extended-release tablets.
- **Injectables**: Significant portion with **6,172 injectable products**, including subcutaneous and IV forms.
- **Topical Products**: Important forms include **creams (457)** and **ointments (244)**.
- **Specialized Forms**: Notable forms like **transdermal films** and **inhalation solutions** serve niche needs.

Overall, oral and injectable forms dominate, with diverse specialized products for targeted therapies.



3.2 Top Dosage Forms by Total Approvals

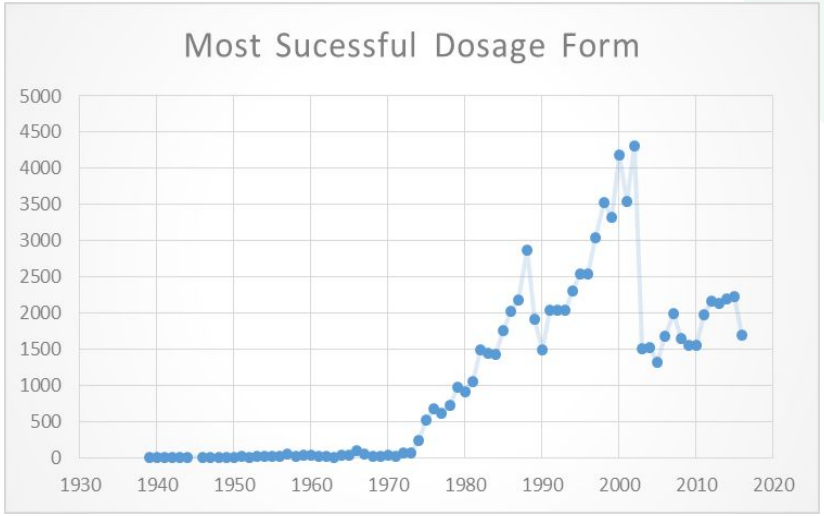
1. **Tablets (Oral)**: Lead with **81,143 approvals**, making them the most successful dosage form.
2. **Injectables**: Significant with **65,160 approvals**, showing strong market presence.
3. **Capsules (Oral)**: Rank third with **23,125 approvals**.
4. **Extended Release Forms**: Both **tablets (7,778)** and **capsules (4,280)** highlight the demand for controlled-release medications.

These insights reflect the dominance of oral and injectable forms in product approvals.

form	Total No. of Approvals
TABLET;ORAL	81143
INJECTABLE;INJECTION	65160
CAPSULE;ORAL	23125
TABLET, EXTENDED RELEASE;ORAL	7778
CAPSULE, EXTENDED RELEASE;ORAL	4280

3.3 Yearly Trends of Successful Dose

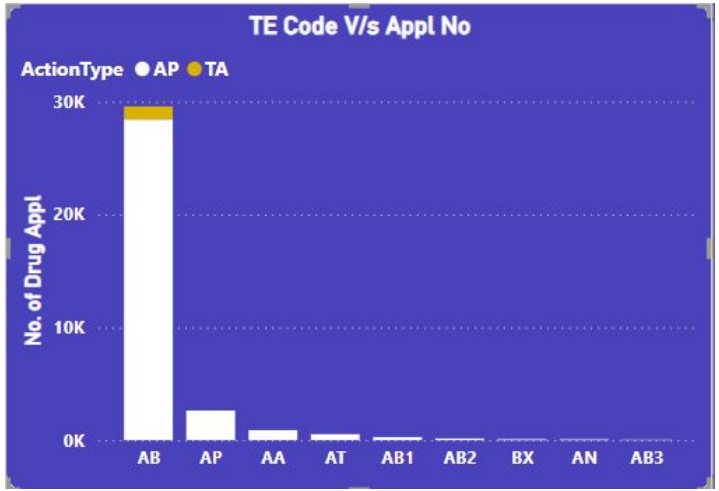
1. **Pre-1960**: Low approval numbers, mostly under 50, indicating minimal market activity for dosage form approvals.
2. **1960s Growth**: Significant increase starts in the mid-1960s, with approvals reaching **94** by 1966, showing early growth in the pharmaceutical industry.
3. **Rapid Expansion in 1970s**: A rapid surge occurs, with approvals jumping to **520 in 1975** and continuing to grow, reaching **725 in 1978**.
4. **1980s Boom**:The 1980s show consistent high growth, with approvals surpassing **1,000 in 1981** and peaking at **2,877 by 1988**.
5. **Peak in 1990s**: The 1990s mark a major expansion, with approvals hitting **3,040 in 1997** and continuing to rise.
6. **2000s Plateau**: Approvals remain high, with a peak of **4,318 in 2002**, followed by a steady plateau around **3,000–4,000** during the early 2000s.
7. **Stability Post-2010**: Approvals stabilize in the 2010s, averaging between **1,500 and 2,200** annually, indicating a mature but stable market.

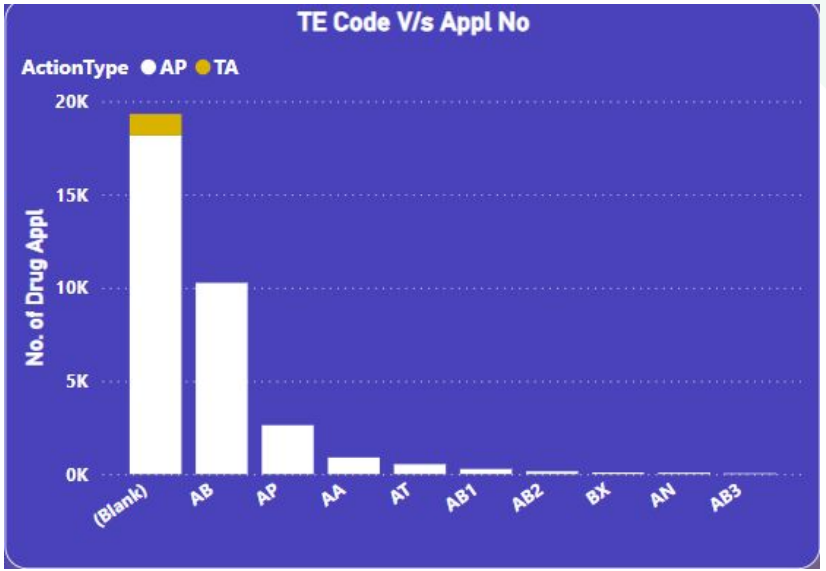


Steady growth in approvals from the 1960s through the 1990s. Peaks in the late 1990s and early 2000s, followed by a plateau and stabilization in the 2010s.

4.1 Drug Approvals by TE_Code

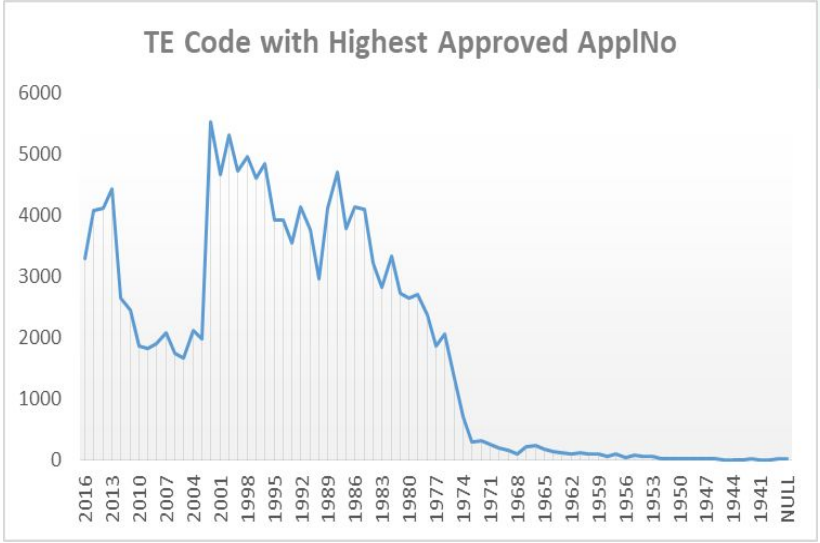
- **Dominant Category**: **NULL** leads with **approvals**, likely unclassified drugs.
- **Top TE_Codes**: **AB** and **AP** are the most common active codes.
- **Notable Others**: **AT** and **AA** show significant activity.
- **Less Common Codes**: **AB1** and **BX** are smaller but relevant.
- **Rare Codes**: **BT**, **AT2**, and **BD** have very few approvals.



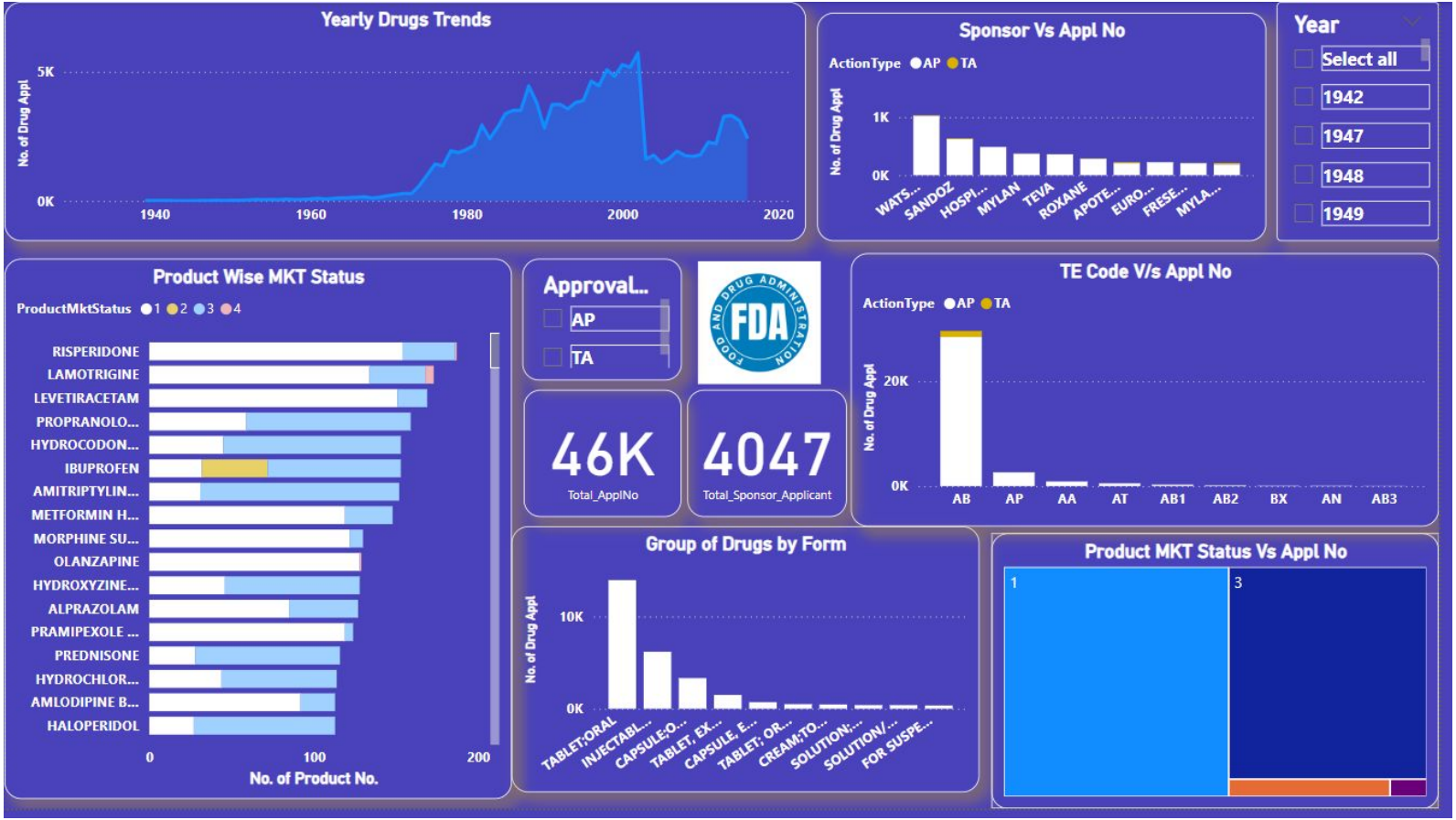


4.2 Drug Approvals by TE_Code

1. **Peak in Early 2000s**: Approvals peaked in **2002** with **5,542 approvals**, with high activity in **2000** and **2001**.
2. **Late 1990s Growth**: Significant growth, with **4,975 approvals in 1998** and **4,618 in 1997**.
3. **Decline Post-2014**: Approvals dropped steadily after **2014**, reaching **3,308 by 2016**.
4. **1980s Surge**: Strong growth in the 1980s, peaking at **4,705 in 1988**.
5. **Low Activity Pre-1975**: Approvals were generally below **1,000** until **1975**.

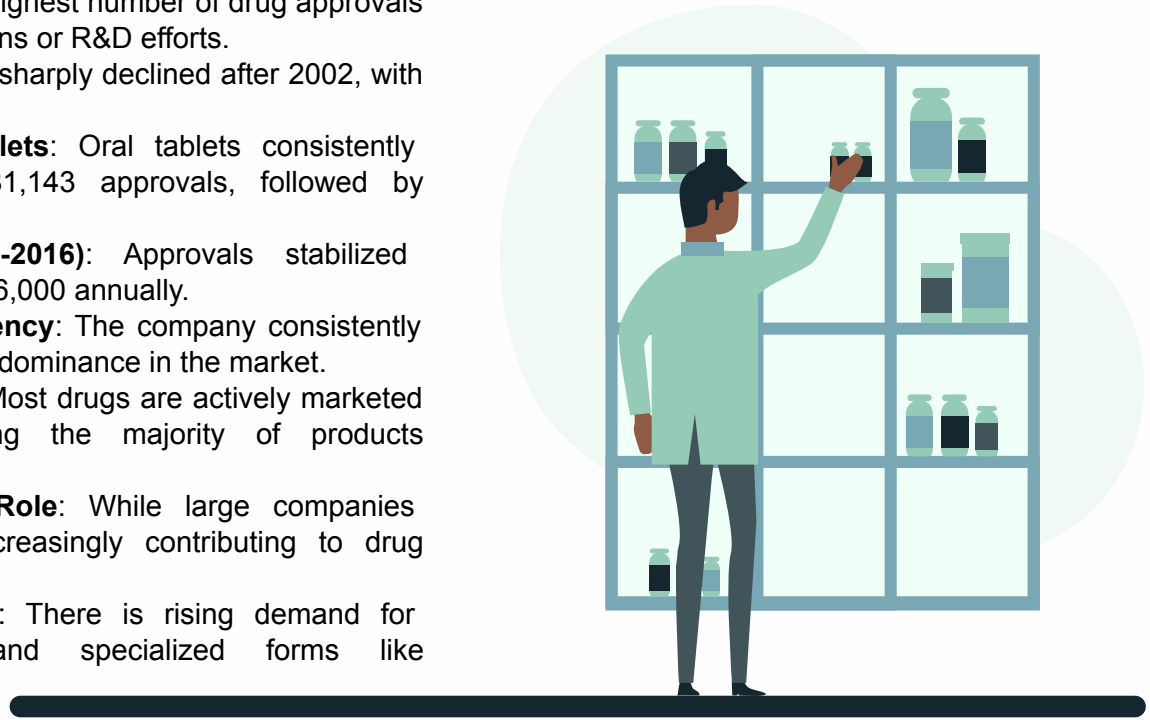


Power Bi Dashboard



Conclusion

- **2002 Peak**: The year 2002 had the highest number of drug approvals (5,661), driven by favorable regulations or R&D efforts.
- **Post-2002 Decline**: Drug approvals sharply declined after 2002, with fluctuations between 2012 and 2016.
- **Market Dominance by Oral Tablets**: Oral tablets consistently dominate drug approvals, with 81,143 approvals, followed by injectables.
- **Stable Approval Trends (2010-2016)**: Approvals stabilized post-2010, averaging around 5,000–6,000 annually.
- **Merck Sharp & Dohme's Consistency**: The company consistently leads in drug approvals, maintaining dominance in the market.
- **ProductMktStatus 1 Dominance**: Most drugs are actively marketed (ProductMktStatus 1), representing the majority of products approved.
- **Smaller Companies' Emerging Role**: While large companies dominate, smaller players are increasingly contributing to drug approval spikes.
- **Shift Toward Specialized Forms**: There is rising demand for controlled-release medications and specialized forms like transdermal films.



SWOT Analysis

Strengths

- Strong FDA regulatory framework ensuring drug safety and efficacy.
- Market leadership by companies like Merck Sharp & Dohme.
- Dominance of widely accepted oral and injectable dosage forms.

Weakness

- Fluctuations in drug approvals post-2002.
- Limited growth in specialized dosage forms like transdermal films.

Opportunities

- Growing demand for controlled-release medications.
- Collaborations with emerging pharmaceutical companies.

Threats

- Regulatory uncertainty affecting approvals.
- Intense competition in the pharmaceutical industry.

Recommendations

1. **Focus on Oral and Injectable Forms**: Given the dominance of these dosage forms, pharmaceutical companies should continue prioritizing innovation and market penetration in these areas.
2. **Monitor Regulatory Shifts**: The fluctuations in drug approvals suggest that regulatory changes significantly impact the market. Continuous monitoring of FDA regulations and policies is crucial for predicting approval trends.
3. **Target Controlled-Release Products**: The rising demand for extended-release forms highlights the importance of investing in research for more convenient and effective therapies.
4. **Support for Smaller Players**: Encourage partnerships with smaller pharmaceutical companies that are increasingly contributing to the approval landscape.

Thanks!