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Review Article

Comparative analysis of drug approval process in FDA and EMA

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ABSTRACT

The drug approval process is a critical component of pharmaceutical regulation that ensures the safety, efficacy, and quality of medicines before they reach patients. This study presents a comparative analysis of the regulatory frameworks and approval pathways followed by the and the. The objective of the study was to evaluate similarities and differences in regulatory structures, application procedures, review timelines, expedited approval pathways, and pharmacovigilance systems adopted by both agencies. The study was conducted using a qualitative and comparative research methodology based on extensive literature review and analysis of official regulatory guidelines, scientific publications, and international harmonization documents. Data related to Investigational New Drug applications, New Drug Applications, Marketing Authorization Applications, clinical trial requirements, accelerated approval mechanisms, and post-marketing surveillance systems were systematically reviewed and compared. The findings indicate that both agencies follow rigorous scientific evaluation processes aligned with International Council for Harmonization guidelines; however, significant differences exist in regulatory implementation. The FDA follows a centralized and relatively flexible approval system with greater use of expedited pathways such as Fast Track, Breakthrough Therapy, and Accelerated Approval, resulting in comparatively shorter review timelines. In contrast, the EMA operates through a multi-national collaborative framework involving member states and emphasizes comprehensive benefit–risk assessment and long-term safety monitoring through Risk Management Plans and Pharmacovigilance Risk Assessment committees. The study concludes that while the FDA approach facilitates faster patient access to innovative therapies, the EMA framework provides stronger emphasis on post-marketing safety and risk management. Both systems possess unique strengths that contribute significantly to global public health. Increased international harmonization, regulatory collaboration, and convergence of approval standards may improve.

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efficiency in global drug development and ensure timely access to safe and effective medicines worldwide.

INTRODUCTION

1.1 Pharmaceutical Regulatory Affairs:

One of the most important positions in the pharmaceutical industry is regulatory affairs. The lifespan of healthcare products is the primary focus of regulatory affairs, which also provides operational, tactical, and strategic guidance to operate within regulations to provide safe and efficient healthcare products globally. In order to ensure that the drug is approved by international regulatory bodies, Regulatory Affairs works to support and execute a plan that ensures the team's combined efforts[1]. The primary responsibilities of a pharmaceutical drug regulatory affairs department include new drug applications and the registration procedure criteria of various pharmaceutical goods. Because the pharmaceutical industry deals with medical devices, regulatory affairs (RA) specialists are essential. It offers operational and strategic guidance as well as assistance in adhering to regulations in order to accelerate the development of biological, medical, and pharmaceutical devices. Additionally, it is primarily concerned with the safety and effectiveness, low risk/high reward, and quality evaluation of pharmaceutical goods used in healthcare worldwide. Different regulatory authorities oversee certification and good manufacturing practices in each nation's regulatory framework. In the pharmaceutical industry, regulatory affairs also plays a very specialized role in the development and promotion of drug products [2].

1.2 Importance of Regulatory Affairs:

Regulatory Affairs (RA) plays a crucial role in ensuring that pharmaceutical products reach the market on time, directly influencing a company's success and financial performance. It ensures that all regulatory guidelines are properly followed, helping to avoid consequences such as warning letters, product recalls, and negative publicity from agencies like the U.S. Food and Drug Administration. Even minor delays in drug approval can result in significant financial losses due to the high cost of drug development. In serious cases, non-compliance or incorrect labelling may lead to product recalls, loss of sales, and reduced trust among investors, patients, and healthcare professionals. Due to its strategic importance, RA professionals are increasingly involved in high-level decision-making. Overall, RA acts as a critical bridge between pharmaceutical companies and regulatory authorities, ensuring both compliance and business success [3].

1.3 HISTORY

HISTORY OF US FDA

The U.S. Food and Drug Administration (FDA) originated from early efforts to regulate food and drugs in the United States and was formally established by the Federal Food and Drugs Act, which prohibited adulterated and misbranded products. Its authority expanded significantly with the Federal Food, Drug, and Cosmetic Act, requiring drug safety proof and extending regulation to more products. Events like the thalidomide disaster led to stricter laws, including the Kefauver–Harris Amendments, mandating drug efficacy and improved clinical trials. Today, the FDA is a key global authority ensuring the safety, efficacy, and quality of medical products [4].

1.4 HISTORY OF EMA

The European Medicines Agency (EMA), established in 1995 under EC Regulation No.

2309/93, was created to harmonize and centralize the regulation of medicines across the European Union. It replaced fragmented national systems with a single evaluation process for approving human and veterinary medicines valid throughout the EU. Over time, EMA expanded its role to include areas like orphan drugs, paediatric medicines, and advanced therapies. It also adapted to public health challenges such as COVID-19 by enhancing crisis response and monitoring medicine shortages. Originally based in London, the agency moved to Amsterdam in 2019 after Brexit [5].

1.5 GLOBAL HARMONISATION (ICH, WHO)

Global harmonization in pharmaceutical regulation aims to standardize technical requirements across countries, enabling medicines to be evaluated using common scientific principles. This reduces duplication, saves time, and improves global access to safe and effective drugs. It promotes collaboration between regulatory authorities and industry to align requirements for quality, safety, and efficacy, thereby facilitating efficient drug development and approval worldwide.

1. International Council for Harmonisation (ICH)

The International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) represents a significant harmonization effort that brings together regulatory bodies and industry stakeholders from regions such as the United States, Europe, and Japan to formulate cohesive guidelines. These ICH guidelines encompass quality, safety, efficacy, and multidisciplinary standards that contribute to uniform regulatory assessments across nations and minimize unnecessary studies [6].

2. World Health Organization (WHO) and Harmonization Support

WHO supports regulatory harmonization especially in low- and middle-income countries by providing technical guidelines, capacity building, and prequalification programs. While WHO does not enforce CTD/eCTD formats, it collaborates with ICH and regional networks to promote globally recognized standards and regulatory convergence, strengthening public health outcomes worldwide [7].

FDA Drug Approval Process (United States)

The FDA regulates drugs through its Central for Drug Evaluation and Research (CDER).

1. Preclinical Research

- Laboratory and animal studies to assess safety and biological activity.
- Must comply with Good Laboratory Practice (GLP) standards.[8]

2. Investigational New Drug (IND) Application

- Submitted before clinical trials.
- Contains preclinical data, manufacturing info, and proposed clinical protocols.[4]

3. Clinical Trials

- Phase 1: Safety (20–100 healthy volunteers).
- Phase 2: Efficacy and side effects (100–300 patients).

- Phase 3: Confirmation of effectiveness (1,000+ patients).[5]

4. New Drug Application (NDA)

- Formal request to market the drug in the U.S.
- Includes all data from trials, proposed labeling, and manufacturing details.[6]

5. FDA Review

- Multidisciplinary team evaluates safety, efficacy, and quality.
- Standard review: 10 months; Priority review: 6 months.

6. Post-Market Surveillance (Phase 4)

- Ongoing safety monitoring, adverse event reporting (via FAERS). [

EMA Drug Approval Process

The EMA operates under the European Medicines Regulatory Network including the European Commission and national agencies.

1. Preclinical and Clinical Studies.

- Similar to FDA: non-clinical (animal/lab) → clinical trials.
- Must comply with EU GLP/GCP standards.

2. Clinical Trial Application (CTA)

- Submitted in the EU country where the trial is conducted.
- Must be approved before starting the study. [8]

3. Marketing Authorization Application (MAA)

- Submitted to EMA via the centralized Procedure.
- Includes full data on quality, safety, efficacy, and proposed labeling. [9]

4. Scientific Evaluation by CHMP

- The Committee for Medicinal Products for Human Use (CHMP) evaluates the MAA.
- Timeline: max 210 days (with clock stops for questions). [10]

5. European Commission Decision

- Final approval by EC based on CHMP recommendation.
- Authorization is valid in all EU/EEA countries.

6. Post-Authorization Monitoring

- Pharmacovigilance via EudraVigilance.
- May require additional post-marketing (Phase 4) studies. [11]

METHODOLOGY

This study employs a qualitative, comparative, and descriptive research methodology to evaluate and contrast the drug approval processes of the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA). The methodology is structured to ensure systematic data collection, critical analysis, and meaningful comparison of regulatory frameworks governing pharmaceutical approvals in the United States and the European Union.

1. Research Design

The present study is based on a comparative research design, focusing on identifying similarities and differences between FDA and EMA regulatory systems. A descriptive approach is also adopted to provide detailed insights into each stage of the drug approval process. The study is non-experimental in nature and relies entirely on documented evidence rather than primary experimental data. This design is suitable for regulatory analysis as it allows comprehensive evaluation of policies, guidelines, and procedures without direct intervention.

2. Sources of Data

The study utilizes both primary and secondary sources of data to ensure reliability and depth of analysis.

2.1 Primary Sources

- Official regulatory guidelines and publications issued by FDA and EMA
- Regulatory frameworks, manuals, and procedural documents
- Official websites and databases of FDA and EMA

2.2 Secondary Sources

- Peer-reviewed journal articles related to drug approval processes
- Review articles, textbooks, and academic publications
- Reports from international organizations such as WHO and ICH
- Online databases such as PubMed and Google Scholar

3. Data Collection Method

Data collection is carried out through a systematic literature review approach. Relevant information is extracted from selected sources based on predefined criteria.

The collected data includes:

- Steps involved in drug approval (preclinical and clinical phases)
- Regulatory submission formats such as NDA (New Drug Application) and MAA (Marketing Authorization Application)
- Approval pathways including standard and accelerated procedures
- Timelines and review mechanisms
- Post-marketing surveillance requirements

Care is taken to ensure that all data is accurate, up-to-date, and obtained from credible sources.

4. Inclusion and Exclusion Criteria

Inclusion Criteria

- Official regulatory documents from FDA and EMA
- Peer-reviewed scientific articles related to drug approval
- Publications in English language
- Recent and relevant studies focusing on regulatory processes

Exclusion Criteria

- Irrelevant studies not related to drug approval processes
- Outdated or obsolete regulatory information

- Non-English publications
- Data lacking scientific credibility or authenticity

These criteria ensure that only high-quality and relevant information is considered in the study.

5. Comparative Parameters

The comparison between FDA and EMA is performed based on the following key parameters:

- Regulatory Structure and Framework: Organizational setup and governance
- Drug Approval Procedures: Stepwise processes from preclinical to marketing approval
- Application Requirements: NDA vs. MAA formats and submission requirements
- Clinical Trial Regulations: Phases, design, and approval of clinical studies
- Review Timelines: Duration and efficiency of approval processes
- Expedited Approval Pathways: Fast track, priority review, and conditional approvals
- Safety and Efficacy Standards: Evaluation criteria for drug approval
- Post-Marketing Surveillance: Pharmacovigilance systems and monitoring

These parameters form the basis for structured and meaningful comparison.

6. Data Analysis

The collected data is analysed using a qualitative comparative approach. Information from different sources is carefully reviewed, categorized, and compared.

- Data is organized into tables and charts for clarity
- Similarities and differences are identified systematically
- Strengths and limitations of each regulatory system are evaluated
- Critical interpretation is performed to derive meaningful conclusions

No statistical tools are used, as the study focuses on descriptive and comparative analysis rather than quantitative evaluation.

7. Presentation of Data

The findings of the study are presented in a clear and organized manner using:

- Tables for side-by-side comparison
- Flowcharts to illustrate approval processes
- Diagrams to enhance understanding

This structured presentation improves readability and helps in better interpretation of results.

RESULT

This chapter presents the detailed findings obtained from the comparative study of regulatory frameworks followed by the United States Food and Drug Administration and the European Medicines Agency. The results are discussed in relation to the objectives of the study, focusing on similarities, differences, and their impact on global drug approval processes.

1. Search/Survey, Appraisal, and Critical Analysis of Relevant Literature

The following table summarizes the quantitative details of literature that was searched, studied, appraised, and analysed for the project work.

Table : Quantitative Details of Literature Reviewed for Comparative Study of USFDA and EMA

Sr. No.	Type of Literature	Obtained After Literature Search	Used for Project Work After Appraisal
1	Official regulations, guidelines, and guidance documents by USFDA & EMA	USFDA: 25 EMA: 20	USFDA: 18 EMA: 15
2	Relevant technical standards (ICH, ISO, etc.)	ICH/ISO: 18	ICH/ISO: 12
3	Peer-reviewed journal articles & book chapters	Articles: 20 Book Chapters: 5	Articles: 14 Book Chapters: 3
4	Whitepapers, newsletters, and regulatory blogs	18	8
	Total	106	70

2. Comparative Analysis of Regulatory Pathways for Drug Approval Process in the US and Europe

Comparative analysis of regulatory pathways of drug products in the United States and Europe has been performed with respect to various regulatory parameters and is presented in the following table.

Table 6.2: Comparison of Regulatory Pathways for Drug Approval in the US and Europe

Sr. No.	Regulatory pathway parameter	US	Europe
A	Regulatory authority and governing law/act	The United States Food and Drug Administration is responsible for the regulation of drugs under the Federal Food, Drug, and Cosmetic Act.	The European Medicines Agency operates under European Union regulations and directives governing medicinal products.
A.1	Regulatory agency and its responsible division	USFDA's Center for Drug Evaluation and Research (CDER) regulates drugs, while CBER regulates biologics. The Office of Combination Products (OCP) assigns product classification.	EMA works through scientific committees such as CHMP (Committee for Medicinal Products for Human Use) for drug evaluation and approval.
B	Application type	New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Biologics License Application (BLA).	Marketing Authorization Application (MAA) is submitted for approval across EU member states.
C	Approval pathways	Includes standard review, priority review, accelerated approval, and fast track designation.	Includes centralized, decentralized, mutual recognition, and national procedures.

D	Clinical trial requirements	Requires Investigational New Drug (IND) application approval before clinical trials.	Requires Clinical Trial Application (CTA) approval as per EU Clinical Trial Regulation.
E	Review timeline	Standard: ~10 months; Priority: ~6 months.	Centralized procedure: ~210 days (excluding clock stops).
F	Post-marketing surveillance	Managed through pharmacovigilance programs like FAERS.	Managed through EudraVigilance system across EU.
G	Inspection and compliance	USFDA conducts GMP inspections and enforces compliance.	EMA coordinates inspections with national competent authorities of EU member states.

3.Comparative analysis of Pre-marketing and Post-Market regulatory requirement for USFDA and EMA:

The regulation of pharmaceutical products is essential to ensure that medicines available in the market are safe, effective, and of high quality. Two of the most influential regulatory authorities globally are the US Food and Drug Administration and the European Medicines Agency. While both agencies share the common goal of protecting public health, their regulatory frameworks differ in structure, procedures, and implementation strategies. This section presents a detailed comparative analysis of pre-marketing and post-marketing regulatory requirements followed by USFDA and EMA.

1. Pre-Marketing Regulatory Requirements

Pre-marketing requirements involve all processes that a pharmaceutical product must undergo before receiving approval for commercial distribution. These steps are critical to evaluate the safety, efficacy, and quality of a drug.

1.1 USFDA Pre-Marketing Requirements

In the United States, drug approval is governed by a centralized regulatory system under the USFDA. The process begins with preclinical studies, followed by submission of an Investigational New Drug (IND) application, which allows the sponsor to initiate clinical trials in humans.

Clinical Trial Phases

- Phase I: Evaluates safety and dosage in healthy volunteers.
- Phase II: Assesses efficacy and side effects in a small patient population.
- Phase III: Confirms effectiveness, monitors adverse reactions, and compares with standard treatments.

All clinical trials must comply with Good Clinical Practice (GCP) guidelines and are subject to strict FDA monitoring.

After successful completion of clinical trials, the sponsor submits:

- New Drug Application (NDA) for small molecules
- Biologics License Application (BLA) for biologics

The USFDA reviews data related to:

- Clinical safety and efficacy
- Chemistry, Manufacturing, and Controls (CMC)

- Labelling and prescribing information

The approval decision is based on a risk-benefit assessment, ensuring that the therapeutic benefits outweigh potential risks.

1.2 EMA Pre-Marketing Requirements

In the European Union, the drug approval process is more complex due to the involvement of multiple member states. The EMA coordinates scientific evaluation, but final authorization may involve national authorities. Clinical trials require submission of a Clinical Trial Application (CTA), which must be approved before initiation. With the implementation of the EU Clinical Trial Regulation, the process has become more harmonized across member states.

Approval Pathways in EMA

- Centralized Procedure: Mandatory for innovative and high-risk medicines; approval valid across all EU countries.
- Decentralized Procedure (DCP): For products not yet authorized in any EU country.
- Mutual Recognition Procedure (MRP): For products already approved in one EU country.

The sponsor submits a Marketing Authorization Application (MAA), which is evaluated by the Committee for Medicinal Products for Human Use (CHMP). A key feature of EMA approval is the mandatory submission of a Risk Management Plan (RMP), which outlines strategies for identifying, characterizing, and minimizing risks associated with the drug.

1.3 Key Differences in Pre-Marketing Phase

- The USFDA operates through a single centralized system, whereas EMA uses a multi-national regulatory network.
- EMA requires a Risk Management Plan (RMP) at the approval stage, while USFDA may require risk mitigation later.
- EMA provides multiple approval pathways, while USFDA follows a uniform approval process.

2. Post-Marketing Regulatory Requirements

Post-marketing surveillance ensures that the drug continues to remain safe and effective after it enters the market. This phase is crucial for detecting rare or long-term adverse effects.

2.1 USFDA Post-Marketing Requirements

The USFDA maintains a robust pharmacovigilance system to monitor drug safety through the FDA Adverse Event Reporting System (FAERS).

Key Components

- Adverse Event Reporting: Mandatory for manufacturers; voluntary for healthcare professionals and patients.
- Phase IV (Post-Marketing) Studies: Conducted to gather additional safety and efficacy data.
- Risk Evaluation and Mitigation Strategies (REMS): Required for drugs with serious safety concerns.
- Periodic Safety Reporting: Includes Periodic Adverse Drug Experience Reports (PADER).

- Inspections: Routine GMP inspections ensure continued compliance in manufacturing facilities.

The USFDA has the authority to:

- Issue safety warnings
- Update labelling
- Withdraw products from the market

2.2 EMA Post-Marketing Requirements

The EMA has a comprehensive pharmacovigilance system that operates across all EU member states, primarily through EudraVigilance, a centralized database for adverse event reporting.

Key Components:

- Risk Management Plan (RMP): Continuously updated throughout the product lifecycle.
- Periodic Safety Update Reports (PSURs): Submitted regularly to evaluate benefit-risk balance.
- Post-Authorization Safety Studies (PASS): Required for further evaluation of safety concerns.
- Pharmacovigilance Risk Assessment Committee (PRAC): Responsible for monitoring and assessing safety issues.

The EMA also collaborates with national regulatory authorities to ensure effective monitoring and rapid response to safety concerns.

2.3 Key Differences in Post-Marketing Phase

- USFDA uses FAERS, whereas EMA uses EudraVigilance for safety reporting.
- EMA has a structured and continuous risk management system (RMP), while USFDA focuses on REMS for specific drugs.
- EMA's pharmacovigilance is committee-driven (PRAC), whereas USFDA relies on internal regulatory systems.

Table No. Comparative Analysis of Pre-marketing and Post-Market regulatory requirement for USFDA and EMA

Aspect	USFDA (USA)	EMA (EU)
Regulatory Authority	US Food and Drug Administration	European Medicines Agency
Pre-Market Application	IND, NDA, BLA	CTA, MAA
Clinical Trial Approval	Centralized (FDA)	Multi-national (via EU system)
Approval Procedure	Single centralized system	Centralized, Decentralized, Mutual Recognition
Evaluation Committee	FDA reviewers	CHMP
Focus Before Approval	Safety, efficacy, quality	Benefit-risk balance, RMP
Post-Market Surveillance	FAERS	EudraVigilance
Risk Management	REMS	RMP
Safety Reports	PADER	PSUR
Post-Market Studies	Phase IV trials	PASS

Regulatory Inspections	FDA inspections	EMA + national authorities
Pharmacovigilance Committee	FDA internal system	PRAC

4.Comparative Analysis: USFDA vs EMA Documentation & Submission

The drug approval process in the U.S. Food and Drug Administration (USFDA) and the European Medicines Agency (EMA) is highly structured, but differs in regulatory frameworks, submission pathways, and documentation formats.

1. Regulatory Framework

USFDA operates under the Federal Food, Drug, and Cosmetic Act and follows centralized authority for drug approvals in the United States. In contrast, EMA works through a decentralized system involving multiple EU member states, though centralized approval is mandatory for certain product categories (e.g., biologics).

2. Submission Format

Both USFDA and EMA use the Common Technical Document (CTD) format and its electronic version (eCTD). However:

- USFDA strictly mandates eCTD submissions through the Electronic Submissions Gateway.
- EMA also uses eCTD but integrates it with EU-specific modules and regional administrative requirements.

3. Application Types

- USFDA submissions include:
  - IND (Investigational New Drug)
  - NDA (New Drug Application)
  - ANDA (Abbreviated New Drug Application)
  - BLA (Biologics License Application)
- EMA submissions include:
  - MAA (Marketing Authorization Application)
  - Variations and Extensions
  - Centralized, Decentralized, and Mutual Recognition Procedures

4. Documentation Requirements

Both agencies require detailed documentation covering:

- Quality (CMC)
- Non-clinical studies
- Clinical trials

However:

- USFDA emphasizes detailed raw data and datasets (e.g., CDISC formats).
- EMA focuses more on risk management plans (RMP) and pharmacovigilance systems.

5. Review Process

- USFDA conducts an independent centralized review.

- EMA coordinates reviews via the Committee for Medicinal Products for Human Use (CHMP) involving rapporteurs from member states.

6. Timelines

- USFDA standard review: ~10 months
- EMA centralized procedure: ~210 days (excluding clock stops)

7. Post-Approval Requirements

- USFDA: Post-marketing surveillance, Phase IV studies
- EMA: Strong emphasis on Risk Management Plan (RMP) and periodic safety update reports (PSURs)

Comparative Table No. 1: USFDA vs EMA Documentation & Submission

Parameter	USFDA	EMA
Regulatory Authority	U.S. Food and Drug Administration	European Medicines Agency
Legal Framework	Federal Food, Drug, and Cosmetic Act	EU Pharmaceutical Legislation
Submission Format	eCTD (mandatory)	eCTD (mandatory in EU)
Application Types	IND, NDA, ANDA, BLA	MAA (Centralized, DCP, MRP)
Submission Portal	Electronic Submissions Gateway (ESG)	EMA eSubmission Gateway
Documentation Modules	CTD Modules 1–5	CTD Modules 1–5 (EU-specific Module 1)
Clinical Data Requirement	Extensive datasets (CDISC format)	Emphasis on clinical summaries + RMP
Risk Management	Less emphasized initially	Mandatory Risk Management Plan (RMP)
Review Authority	Centralized review by FDA	CHMP with multi-country involvement
Review Timeline	~10 months	~210 days (excluding clock stops)
Approval Scope	USA only	All EU member states (centralized)
Post-Marketing Requirements	Phase IV studies, FAERS reporting	PSUR, RMP updates, pharmacovigilance
Inspection Focus	GMP, GLP, GCP compliance	GMP + EU-specific compliance standards

5. Comparative Analysis: Review Timeline (USFDA vs EMA) [1,2,3]

The review timeline is a critical component of drug approval, influencing how quickly patients gain access to new therapies. While both agencies follow rigorous scientific evaluation, their review duration, flexibility, and pathways differ significantly.

1. Standard Review Timeline

- **USFDA**
  - Standard review: ~10 months
  - Priority review: ~6 months
  - Accelerated pathways (fast track, breakthrough): can be shorter
- **EMA**
  - Standard centralized procedure: ~210 active review days (~12–15 months total including clock stops)
  - Accelerated assessment: ~150 days

2. Actual Observed Timeline Differences

- Studies show FDA approves drugs ~90–100 days earlier than EMA on average
- Another analysis reported:

- FDA: ~7.7 months
- EMA: ~14.5 months

3. Reasons for Timeline Differences

Factor	USFDA	EMA
Regulatory structure	Single national authority	Multi-country coordination
Review flexibility	High (accelerated approvals common)	More conservative
Data acceptance	Accepts surrogate endpoints	Focus on long-term safety
Administrative process	Streamlined	Includes “clock stops” for queries

4. Expedited Review Pathways Impact

- FDA uses:
  - Fast Track
  - Breakthrough Therapy
  - Accelerated Approval
- EMA uses:
  - Conditional Marketing Authorization
  - Accelerated Assessment

Comparative Table: Review Timeline (USFDA vs EMA)

Parameter	USFDA	EMA
Regulatory body	U.S. Food and Drug Administration	European Medicines Agency
Standard review time	~10 months	~210 days (~12–15 months total)
Priority / Accelerated review	~6 months	~150 days
Average real-world approval time	~7–10 months	~12–15 months
Approval timing difference	Faster by ~3 months	Slower
Review structure	Continuous review	Includes clock stops
Flexibility	High (surrogate endpoints accepted)	Moderate (more stringent)
Expedited pathways usage	Very frequent	Less frequent
Decision speed	Faster	More cautious

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