MANAGE ARTWORKS

Allergen Check

Active ingredients

Understanding

FDA Compliance

Requirements for **Pharmaceutical Packaging Artwork**

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Image courtesy: Boots

Pharmacy chain **Boots** recalled more than **110,000 packs of 500-milligram paracetamol tablets** because the outer cardboard packaging is correctly labelled: **"Paracetamol 500mg Tablets"** but the inner foil blister pack of pills instead reads: **"Aspirin 300mg Dispersable Tablets".**

Introduction

Pharmaceutical packaging plays a huge role in ensuring **patient safety.** One wrong detail, whether in terms of **font size, dosage typo,** or **missed warning,** can impact **sales, business reputation, and patient well-being.**

Johnson & Johnson was fined just over **$1.64 billion** in a lawsuit for using **misleading marketing tactics** for two of its HIV meds.

With the **FDA constantly evolving its regulatory requirements, label compliance becomes mandatory.** In this deep dive, we'll walk you through what **FDA compliance** means for **pharmaceutical artwork** and why **getting it right matters more than ever.**

Why **FDA Compliance** can’t be an afterthought?

Marketing teams often want to create packaging that **sells instantly.** The leadership wants to **rush to market** before competitors. Designers have many **creative ideas that don't align well with regulatory requirements.** All of these competing objectives put **compliance at risk.** But here's the thing: **Non-compliance doesn't just cost money. It destroys business reputation and customer trust and loyalty.**

When a **label** goes wrong, the **consequences** are rarely small. This isn’t just about annoying paperwork or **hefty fines** from regulators. This is about **endangering** the **business,** the **brand,** and sometimes **people’s lives.**

The **FDA doesn’t play around with labeling errors.** More than **a thousand pharmaceutical products are recalled yearly for packaging-related issues.** Some of these errors are glaring, such as **missing dosage instructions or wrong lot numbers.** Others are minor but have consequences, from **misaligned barcodes** to **misleading ingredients.**

Dr. Reddy’s recalled **1,000 mg/100 ml** single-dose **levetiracetam** infusion bags because they were incorrectly labeled as **500 mg/100 ml levetiracetam** in **0.82% sodium chloride injection,** while the **aluminum overwrap packaging** correctly identifies the product as **levetiracetam in 0.75% sodium chloride injection 1,000 mg/100 ml.**

The **True Cost** of **Non-Compliance**

Compliance is a critical aspect of **pharma artwork management.** However, **manual approaches** and **traditional tools** cause several **errors** to slip through the gaps that impact **regulatory accuracy.** Teams lack the **transparency** to maintain accurate **compliance records** without proper **audit mechanisms.**

Pharma companies that **fail to comply** with necessary **FDA compliance requirements** experience several **far-reaching consequences** across:

Financial Risks

FDA violations hurt the wallet immediately. A **recall due to labeling** can cost **tens of millions,** sometimes more. It's a **Herculean task** of **reprinting, pulling stock off shelves, reshipping, legal fees,** and **customer service escalations.** The longer it takes to **detect the issue,** the **more expensive** it gets.

Pharmaceutical firm Bristol-Myers Squibb entered a **$700 million** settlement with **Hawaii** in a case about **warning labels** related to **health risks** from **blood thinner Plavix.**

Reputational Risks

One bad recall can create **distrust** in an industry where **credibility** is everything. **Doctors** start to **second-guess** products. **Pharmacists** flag the brand, **patients** look elsewhere, and sales continue to **plummet.**

Sarepta Therapeutics shares closed over **5.3% lower** on Monday, hitting more than a **nine-year low,** and fell another **8.5%** amid **FDA label review** of its **Duchenne muscular dystrophy (DMD)** gene therapy, **Elevidys.**

Operational Risks

Labeling errors cause more than **fines**. They stall **launches, delay shipments, and overload compliance teams.** And they usually require **all-hands-on-deck** firefighting to fix, pulling **resources** from where they're needed.

The **FDA** sent **Sterling Distributors a warning letter** for **poor record-keeping** and **non-compliance** with the **Drug Supply Chain Security Act's requirements.**

Anatomy of

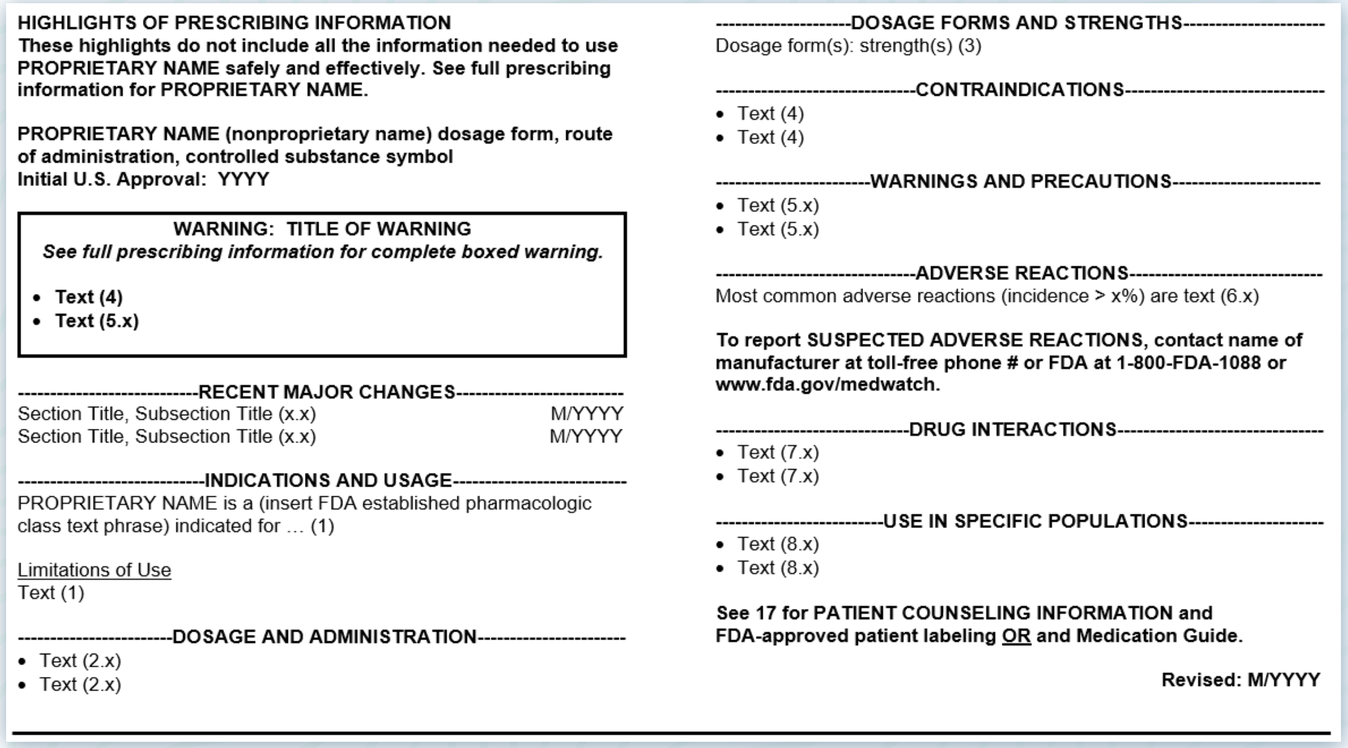
FDA-Approved Pharmaceutical Artwork

At a minimum,

Pharma packaging

artwork should include:

- Brand name
- Generic or non-proprietary name
- Dosage strength
- Route of administration
- Net quantity of contents
- Recommended dosage instructions
- NDC (National Drug Code) number
- Barcode (either UPC or 2D)
- Warnings, precautions, & contraindications
- List of active & inactive ingredients
- Manufacturer or distributor name & contact
- Storage conditions
- Lot number & expiration date



HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use PROPRIETARY NAME safely and effectively. See full prescribing information for PROPRIETARY NAME.

PROPRIETARY NAME (nonproprietary name) dosage form, route of administration, controlled substance symbol
Initial U.S. Approval: YYYY

WARNING: TITLE OF WARNING
See full prescribing information for complete boxed warning.

- **Text (4)**
- **Text (5.x)**

----------RECENT MAJOR CHANGES----------
Section Title, Subsection Title (x.x) M/YYYY
Section Title, Subsection Title (x.x) M/YYYY

----------INDICATIONS AND USAGE----------
PROPRIETARY NAME is a (insert FDA established pharmacologic class text phrase) indicated for … (1)

Limitations of Use
Text (1)

----------DOSAGE AND ADMINISTRATION----------
- Text (2.x)
- Text (2.x)

----------DOSAGE FORMS AND STRENGTHS----------
Dosage form(s): strength(s) (3)

----------CONTRAINDICATIONS----------
- Text (4)
- Text (4)

----------WARNINGS AND PRECAUTIONS----------
- Text (5.x)
- Text (5.x)

----------ADVERSE REACTIONS----------
Most common adverse reactions (incidence > x%) are text (6.x)

To report SUSPECTED ADVERSE REACTIONS, contact name of manufacturer at toll-free phone # or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------DRUG INTERACTIONS----------
- Text (7.x)
- Text (7.x)

----------USE IN SPECIFIC POPULATIONS----------
- Text (8.x)
- Text (8.x)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling OR and Medication Guide.

Revised: M/YYYY

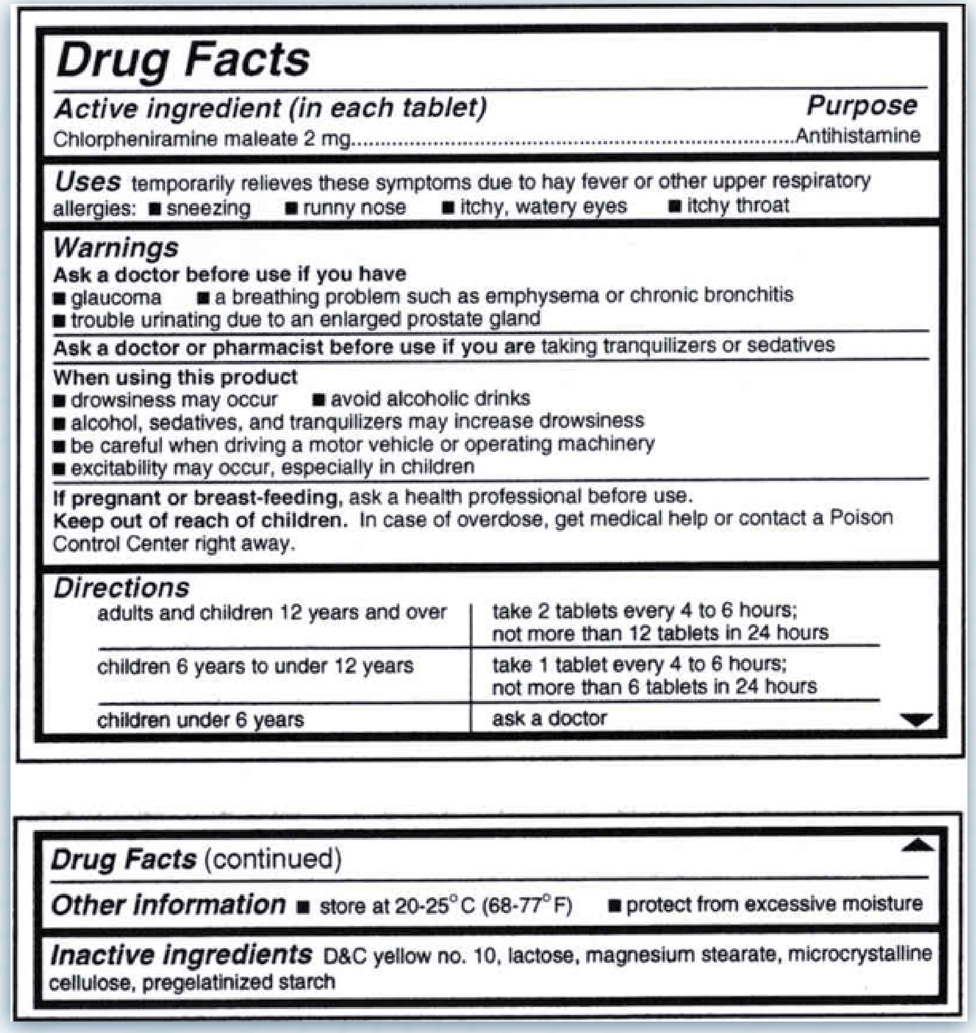
Source: FDA

For
Over-the-counter drugs,
labels should include:

- Drug Facts Panel (with a specific structure)
- Tamper-evident statement
- Consumer-friendly instructions

The **“Rx Only” statement** must be **visible** on the **principal display panel** for **prescription drugs.**

Pharma companies can include **optional elements** like **logos, clinical summaries,** or **marketing messages,** but must **never interfere** with **regulatory information.**



Drug Facts

Active ingredient (in each tablet) ***Purpose***

Chlorpheniramine maleate 2 mg.....Antihistamine

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ sneezing ■ runny nose ■ itchy, watery eyes ■ itchy throat

Warnings

Ask a doctor before use if you have

■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis
■ trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives

When using this product

■ drowsiness may occur ■ avoid alcoholic drinks
■ alcohol, sedatives, and tranquilizers may increase drowsiness
■ be careful when driving a motor vehicle or operating machinery
■ excitability may occur, especially in children

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

adults and children 12 years and over	take 2 tablets every 4 to 6 hours; not more than 12 tablets in 24 hours
children 6 years to under 12 years	take 1 tablet every 4 to 6 hours; not more than 6 tablets in 24 hours
children under 6 years	ask a doctor

Drug Facts (continued)

Other information ■ store at 20-25°C (68-77°F) ■ protect from excessive moisture

Inactive ingredients D&C yellow no. 10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch

Source: FDA

The Challenges of Manual Artwork Compliance

The **pharmaceutical packaging process** usually involves **multiple people,** across teams, working on **dozens of versions** of the same file. Each **packaging artwork copy** goes through **several revisions** before **final approval.** Therefore, each change must be carefully managed to ensure **accuracy, consistency, and compliance** with **FDA regulations.**

However, **manual compliance processes** have several challenges, especially around **version control, approvals,** and **regulatory updates.** Mistakes can range from sending a **non-approved artwork copy** to print to **font size inconsistencies** and **non-alignment with regulatory changes.** In summary, manual artwork compliance can lead to:

01

Delays:

Manual reviews are often built around **long email threads** and **static PDFs.** People check different elements: **text, symbols, dosage tables** manually. Every **market variation** needs a **separate review.**

02

Missed Errors:

The more **repetitive the task,** the easier it is to overlook a **missing word, a comma in the wrong place,** or a **size inconsistency** in the font. These may seem small, but have **costly repercussions.**

03

Scalability Issues:

The **review burden multiplies** as the **product portfolio grows.** What worked for **three SKUs** won't work for **thirty,** especially if they're being launched in **multiple countries with different rules.**

Automating Compliance with Smart Workflows

Automating compliance with smart workflows is an **excellent way** for pharmaceutical companies to navigate the **ever-evolving regulatory landscape.** Modern **automated tools** offer a **range of capabilities** designed for this exact job.

01

Set Custom Rules:

Build compliance rules reflecting **internal** and **regional standards.** From **setting a minimum font size of 6pt** for dosage instructions to **making all Rx labels bold.**

02

Review at Speed:

Once the artwork is uploaded, the system **scans it against set rules.** Teams get a **report** that shows which parts **passed** and what needs **fixing.** They can also **compare versions, highlight differences,** and **tag collaborators** for feedback.

03

Keep an Audit Trail:

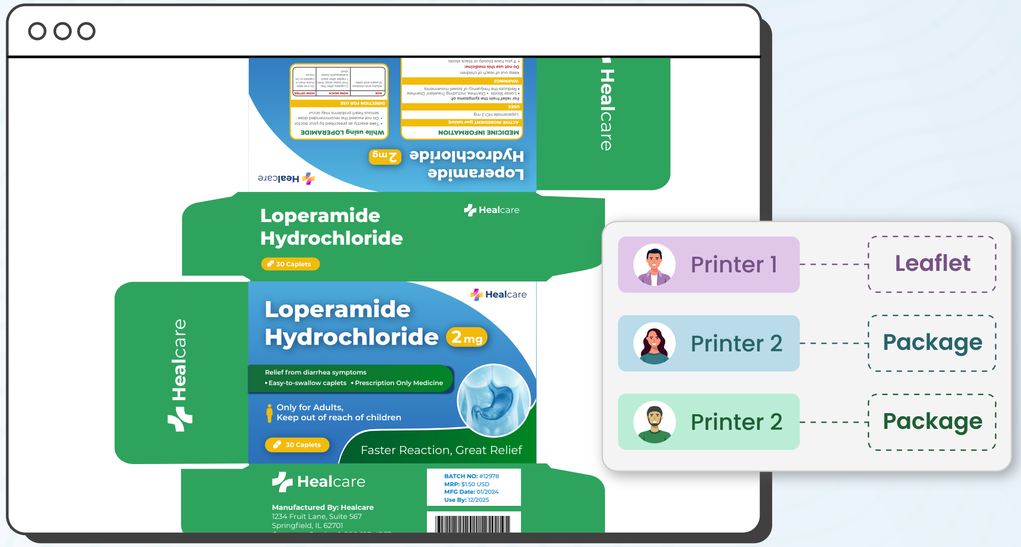
Every action is **tracked:** what **changed,** who **approved it,** and when. This is huge for **internal accountability** and **external audits.**

How **ManageArtworks** makes compliance repeatable

ManageArtworks brings **much-needed structure** to the **chaotic pharma artwork management process.** It's built to **manage complexity,** without **overwhelming** the teams using it. It **centralizes assets** in one place, so teams can **streamline complex compliance processes** and **visualize KPIs** without hassle. **Tracking and auditing activities** ensure **error-free** and **compliant artworks, reducing market time.**

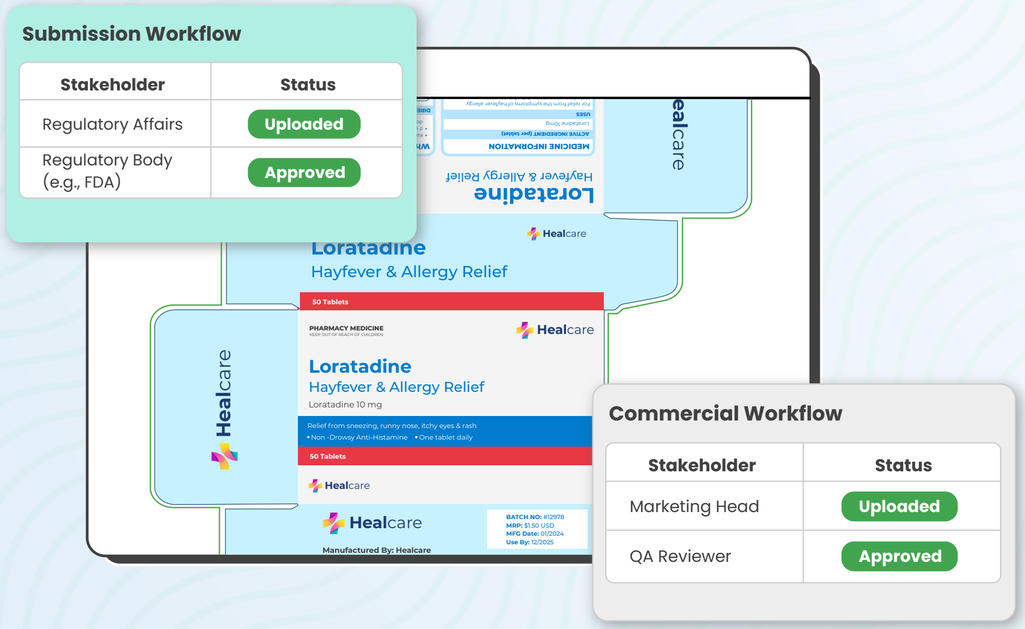
AI Proofing Across Markets:

ManageArtworks adapts to **local compliance needs,** whether **exporting to Brazil** or launching in the U.S. It **scans for regulatory red flags, validates ingredient listings,** and **checks language-specific label elements.**



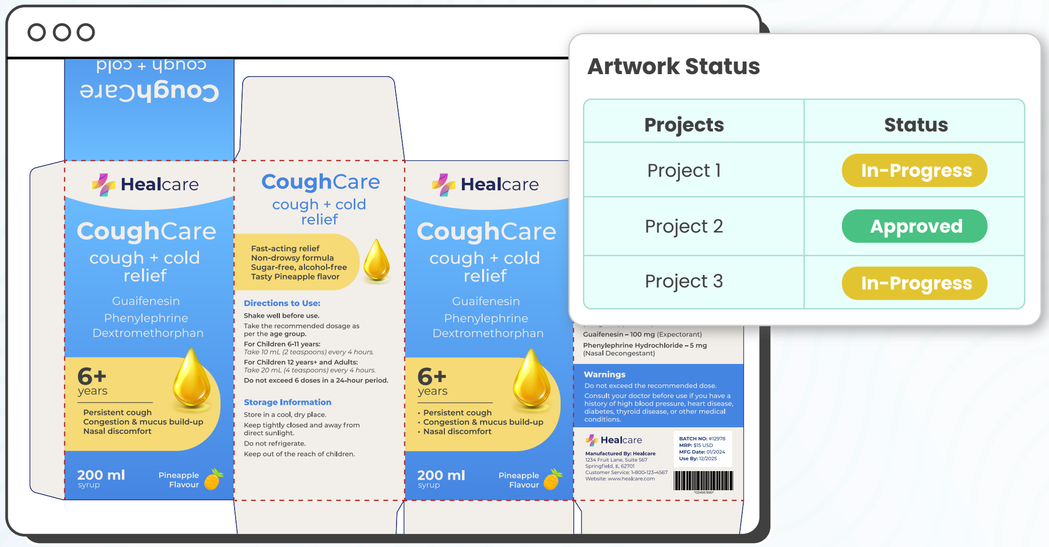
Audit Trails:

Regulatory audits are **much less stressful** when teams can pull up the **review history** of any **artwork version,** complete with **timestamps** and **stakeholder actions.**



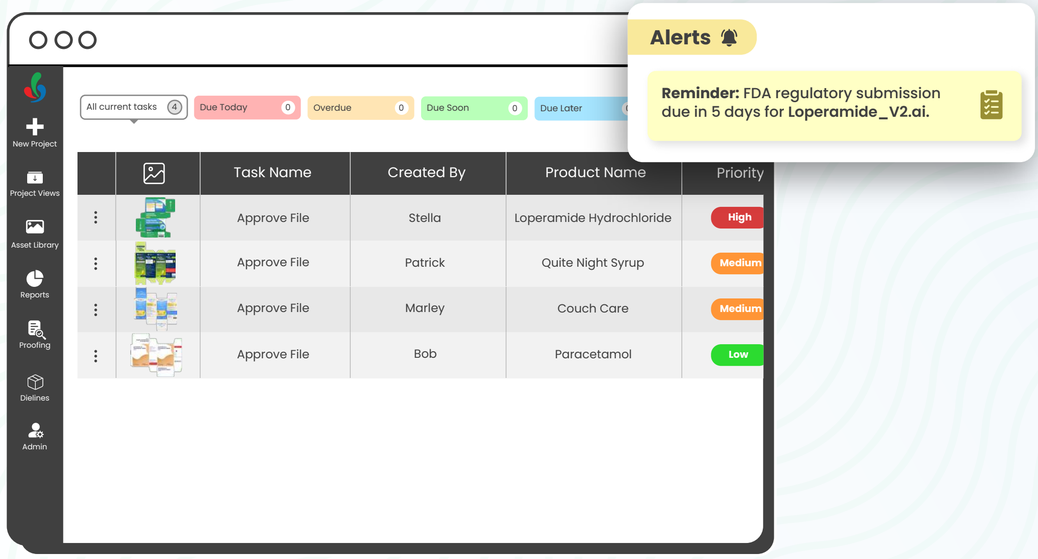
Team Collaboration:

The system **eliminates silos** between **packaging, legal, QA,** and **marketing work** from a **single source of truth. Annotations, approvals, and feedback** all live in **one place.**



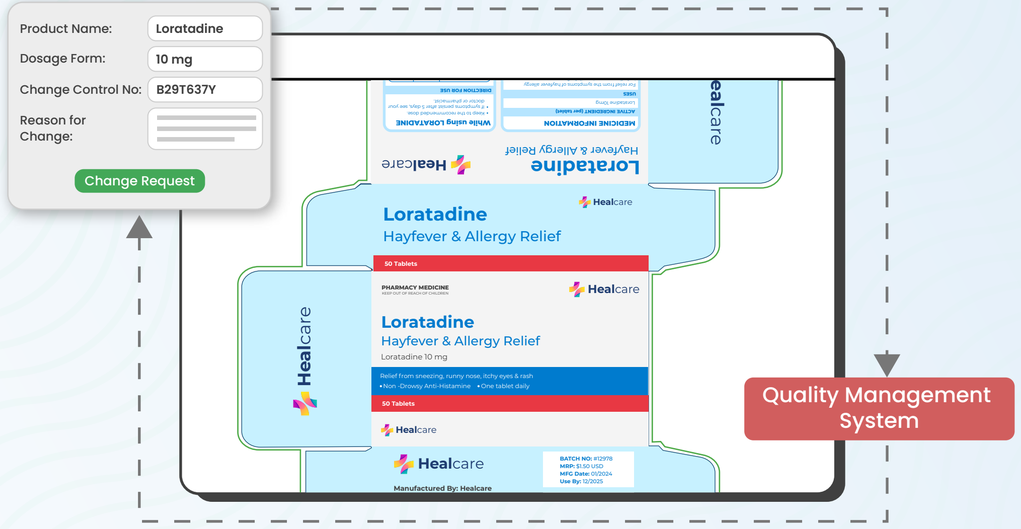
Alerts and Notifications:

With **ManageArtworks,** users are **alerted** when something is **missing, wrong, or needs review.** They no longer need to rely on **inboxes** or **spreadsheets** to **stay compliant.**



Regulatory Environment Monitoring:

ManageArtworks allows **diverse teams** to stay on top of **evolving guidelines.** If the **FDA tweaks a rule,** teams will be **notified.** They can then **update their rulebook,** so every **future label** automatically reflects the **change.** This includes **date tracking** for **compliance deadlines** and **change notifications** across **impacted SKUs.**



Checklist:
Are you FDA ready?

Pharma companies looking to comply with **necessary FDA labeling guidelines** must run **every artwork** through a **checklist.** Here is a **sample:**

Front Panel	Yes / No
Drug name (brand and generic)	
Dosage strength	
Route of administration	
Dosage form(tablet, injection, ointment)	
Quantity	
“Rx Only” (for prescription drugs)	

Ingredient & Warning Info	Yes / No
Active and inactive ingredients	
Allergy warnings (if any)	
Proper warning language (Do not use,Ask a doctor if..., etc)	

Box Warnings	Yes / No
Usage indications	
Dosage instructions	
Contraindications	
Drug interactions	
Manufacturer contact details	

Design Compliance	Yes / No
Fonts, color contrast, alignment	
Logos placed correctly	
Language localization (if needed)	

Barcode & ND	Yes / No
FDA-compliant barcode	
Valid NDC number, clearly placed	

Storage & Usage	Yes / No
Clear instructions	
Lot number	
Expiry date	
Storage and handling directions	

Conclusion

The **pharmaceutical companies thriving** in today's market don't see **compliance** as a burden; they're using it to **build trust and efficiency.** By combining human expertise with **modern compliance management tools,** they're:

- **Reducing time-to-market** by **30-45%**
- **Cutting compliance-related costs** by up to **60%**
- **Building reputations for reliability** that **pay dividends**

FDA labeling compliance isn't just a task; it's **central to the safe distribution of essential drugs** and **market success.**

Manual compliance methods might get the job done for a while. However, **automation** is the **way forward to reduce errors, move faster,** and **scale globally.**

Solutions like **ManageArtworks** offer a **smart, structured, and repeatable process** for getting it right the first time, and every time after that.

If your team still relies on **static PDFs, email approvals,** and memory to manage FDA packaging artwork compliance, **now's the time to switch.**