Using FDA's Inactive Ingredient Database (IID): Best Practices & Considerations

Generic Drugs Forum (GDF) 2026
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Office of Generic Drugs
Center for Drug Evaluation and Research

Outline

- Overview of the IID
- Best Practices: How To Use the IID
- How to Calculate MDE
- GDUFA IID Program Enhancements
- Special Considerations: FD&C Red #3
- Helpful Resources, IID Mailbox & Contact Information

Overview: What is the IID?

Inactive Ingredient Search for Approved Drug Products

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[About this Database] | [Most Recent Changes to the Database] | [Ingredients Database Download]

Search and Browse by Inactive Ingredient

Search for Inactive Ingredient Name*: Search for Inactive Ingredient Name

Submit Clear

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z 0-9

Changes and Deletions by Inactive Ingredient Name

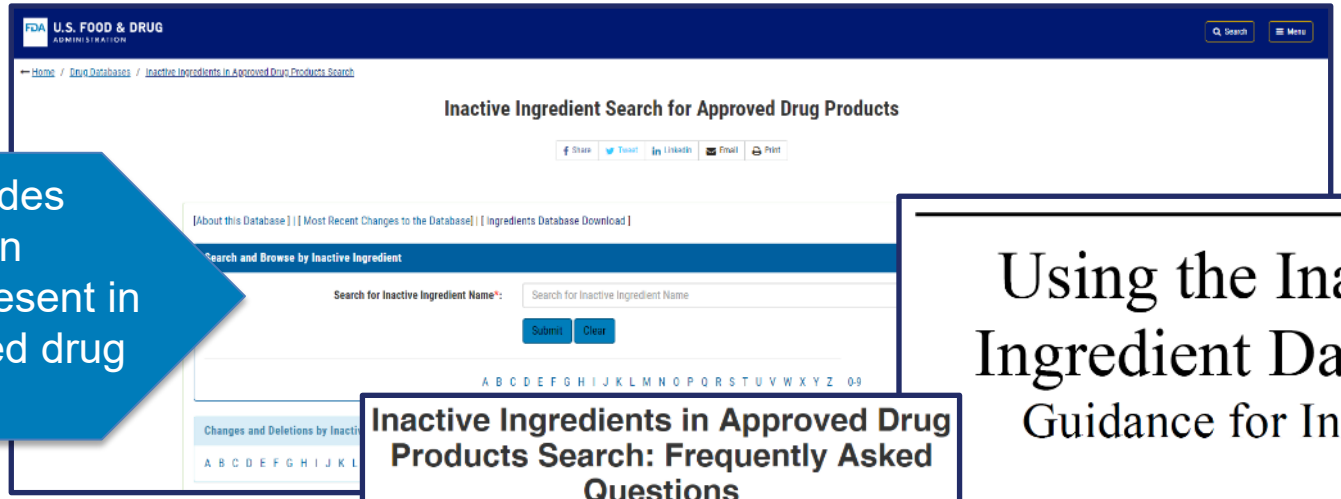
A B C D E F G H I J K L M N O P Q R S T U V W X Y Z View All

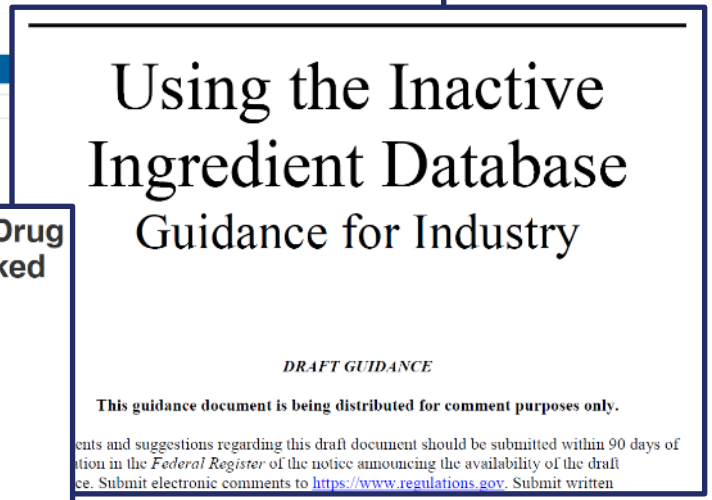
FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
Office of Bioequivalence
Mailbox for IID corrections: IIDUpdate@fda.hhs.gov
Update Frequency: Quarterly

Data Through: June 19, 2025
Database Last Updated: July 18, 2025

Introduction to the IID

The IID provides information on excipients present in FDA-approved drug products.



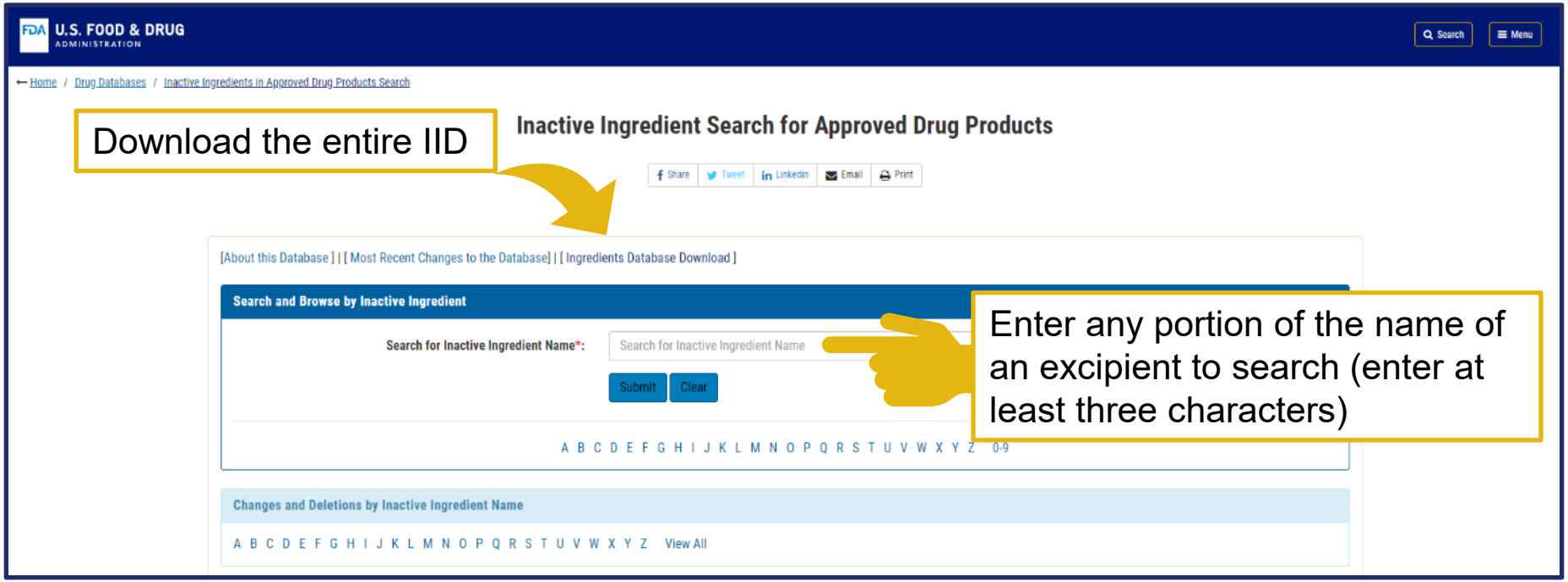


Helpful Resources:
- ✓ FAQs
- ✓ Guidance for Industry

[Inactive Ingredient Search for Approved Drug Products (fda.gov)](#) | [Using the Inactive Ingredient Database Guidance for Industry | FDA](#)

Best Practices: How to Use the IID

How to Use the IID



[Inactive Ingredient Search for Approved Drug Products (fda.gov)]

How to Use the IID (cont.)

Maximum Potency per unit dose

Maximum Daily Exposure (MDE)

Inactive Ingredient	Route	Dosage Form	CAS Number	UNII	Maximum Potency per unit dose	Maximum Daily Exposure (MDE)	Record Updated
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED)	VAGINAL	GEL		HHT01ZNK31		200mg	
CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED)	TRANSDERMAL	GEL, METERED		Z135WT9208	1%w/w		
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED)	TRANSDERMAL	GEL		4Q93RCW27E		90mg	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED)	TRANSDERMAL	GEL, METERED		4Q93RCW27E	1%w/w		
CARBOMER HOMOPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED)	TOPICAL	GEL		F68VH75CJC		8mg	
CARBOMER HOMOPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED)	TOPICAL	LOTION		F68VH75CJC		43mg	Y
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED)	TOPICAL	CREAM		HHT01ZNK31		214mg	

Record

Flag for new records

Displays one row per unique Inactive Ingredient – RoA – DF combination

CAS = Chemical Abstracts Service Registry Number
UNII = Unique Ingredient Identifier assigned by FDA's *Global Substance Registration System* (GSRS)

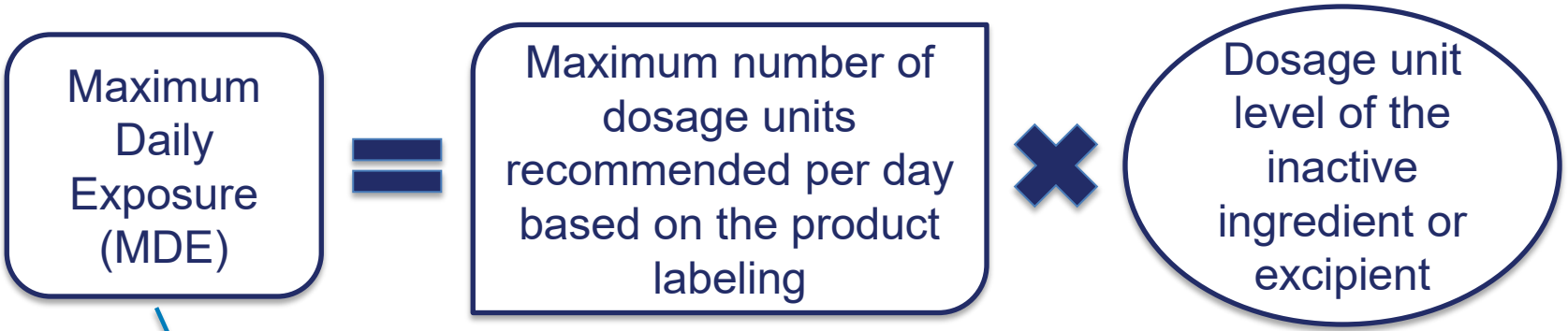
Limitations of the IID

- Does not provide context of use (e.g., duration of exposure, patient population, and indication(s) for use)
- Does not disclose proprietary excipient information (e.g., reference listed drug formulation)
- Does not provide a link between maximum potency and MDE
- Does not include excipients in Biologics License Applications and Over-the-Counter monograph products

*Using the Inactive Ingredient Database Guidance for Industry | FDA

How to Calculate MDE

Excipient Maximum Daily Exposure



MDE is also the Maximum Daily Intake (MDI) for oral drug products

Example:
- Excipient level is 20 mg per dosage unit
- Maximum number of dosage units recommended per day is 2 (per product labeling)
- Then, the Excipient MDE (MDI) is 40 mg
- i.e., 2 dosage units * 20 mg/dosage unit = 40 mg

IID Program Enhancements

IID Enhancements Under GDUFA

GDUFA **II** (Generic Drug User Fee Amendments) Commitment (Fiscal Years 2018-2022)

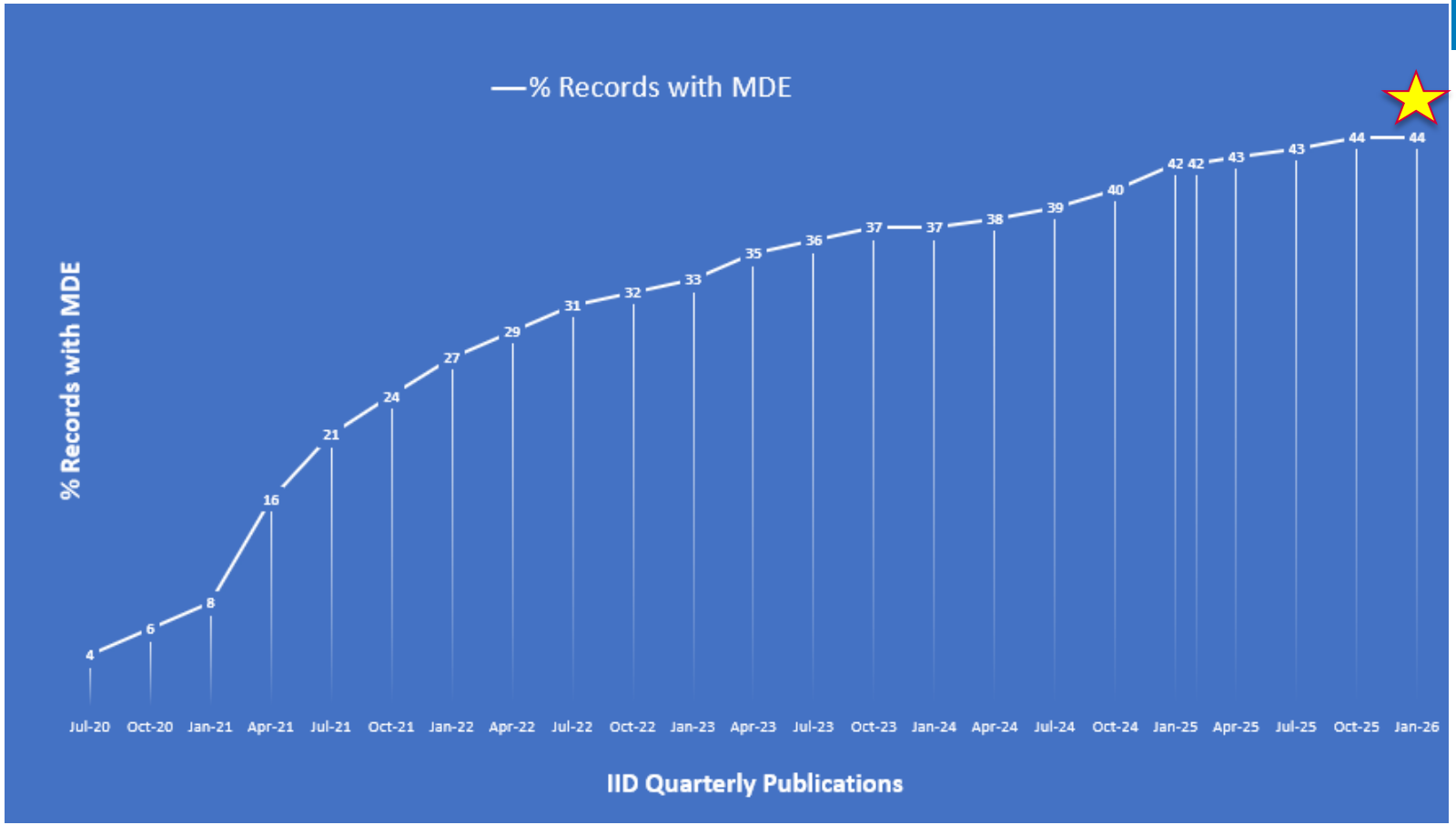
- By October 1, 2020, FDA will complete enhancements to the Inactive Ingredient Database so users can perform electronic queries to obtain accurate Maximum Daily Intake and Maximum Daily Exposure information for each route of administration for which data is available.
- FDA will update the Inactive Ingredient Database on an ongoing basis and post quarterly notice of updates made. Such notices will include each change made and, for each change, the information replaced.

GDUFA **III** Continued Commitment (Fiscal Years 2023-2027)

- FDA will update the Inactive Ingredient Database on an ongoing basis and post quarterly notice of updates made. Such notices will include each change made during the previous quarter, the new information, and the information that was replaced.

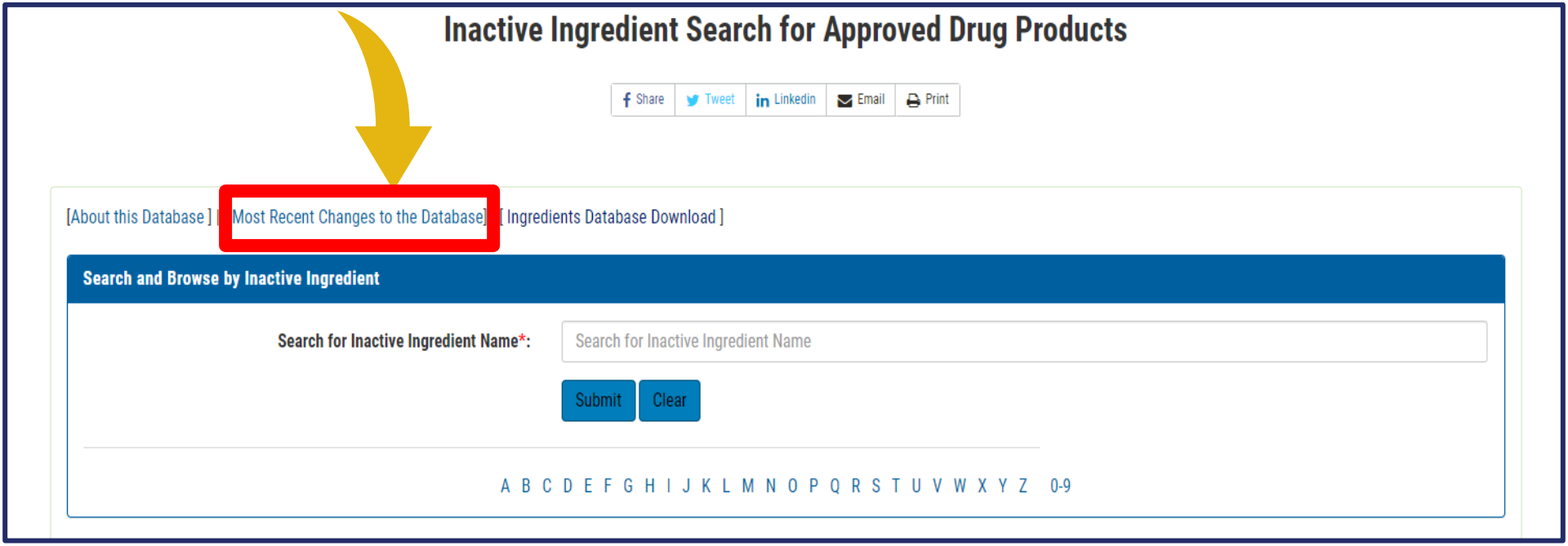
GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2018-2022 and Fiscal Years 2023-2027

Increase in Records with MDE

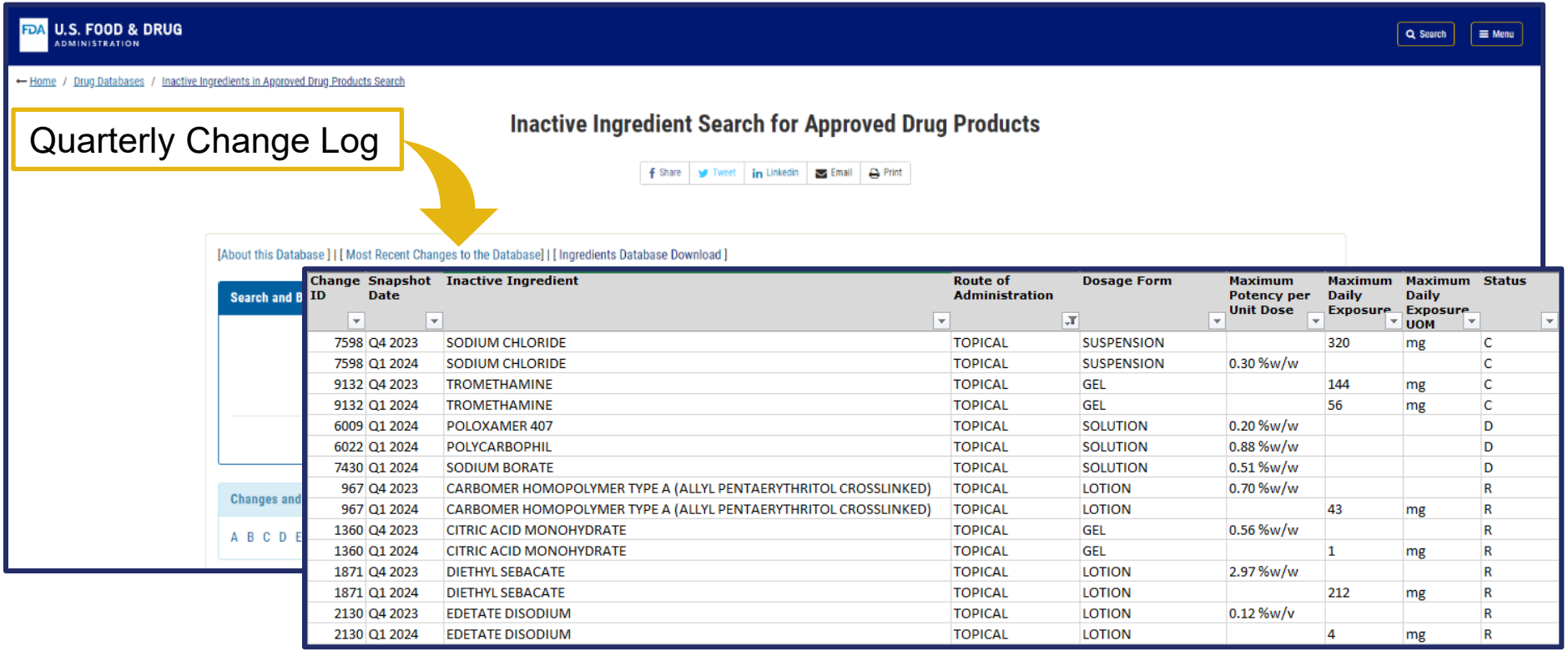


IID Enhancements – Quarterly Change Log

Quarterly Change Log



IID Enhancements – Quarterly Change Log



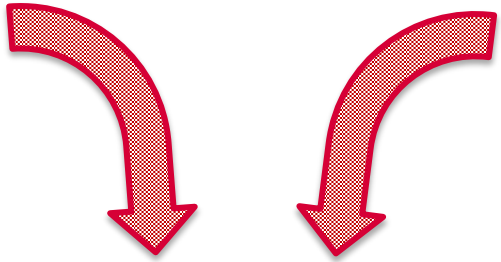
Change ID	Snapshot Date	Inactive Ingredient	Route of Administration	Dosage Form	Maximum Potency per Unit Dose	Maximum Daily Exposure	Maximum Daily Exposure UOM	Status
7598	Q4 2023	SODIUM CHLORIDE	TOPICAL	SUSPENSION		320	mg	C
7598	Q1 2024	SODIUM CHLORIDE	TOPICAL	SUSPENSION	0.30 %w/w			C
9132	Q4 2023	TROMETHAMINE	TOPICAL	GEL		144	mg	C
9132	Q1 2024	TROMETHAMINE	TOPICAL	GEL		56	mg	C
6009	Q1 2024	POLOXAMER 407	TOPICAL	SOLUTION	0.20 %w/w			D
6022	Q1 2024	POLYCARBOPHIL	TOPICAL	SOLUTION	0.88 %w/w			D
7430	Q1 2024	SODIUM BORATE	TOPICAL	SOLUTION	0.51 %w/w			D
967	Q4 2023	CARBOMER HOMOPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED)	TOPICAL	LOTION	0.70 %w/w			R
967	Q1 2024	CARBOMER HOMOPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED)	TOPICAL	LOTION		43	mg	R
1360	Q4 2023	CITRIC ACID MONOHYDRATE	TOPICAL	GEL	0.56 %w/w			R
1360	Q1 2024	CITRIC ACID MONOHYDRATE	TOPICAL	GEL		1	mg	R
1871	Q4 2023	DIETHYL SEBACATE	TOPICAL	LOTION	2.97 %w/w			R
1871	Q1 2024	DIETHYL SEBACATE	TOPICAL	LOTION		212	mg	R
2130	Q4 2023	EDETATE DISODIUM	TOPICAL	LOTION	0.12 %w/v			R
2130	Q1 2024	EDETATE DISODIUM	TOPICAL	LOTION		4	mg	R

Quarterly Inactive Ingredient Database (IID) Change Log | FDA

Quarterly Updates

MDEs from Newly Approved Products

MDEs from Previously Approved Products



Quarterly Updates

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9132	Q4 2023	TROMETHAMINE	TOPICAL	GEL		144	mg	C
9132	Q1 2024	TROMETHAMINE	TOPICAL	GEL		56	mg	C
6009	Q1 2024	POLOXAMER 407	TOPICAL	SOLUTION	0.20 %w/w			D
6022	Q1 2024	POLYCARBOPHIL	TOPICAL	SOLUTION	0.88 %w/w			D
7430	Q1 2024	SODIUM BORATE	TOPICAL	SOLUTION	0.51 %w/w			D
967	Q4 2023	CARBOMER HOMOPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED)	TOPICAL	LOTION	0.70 %w/w			R
967	Q1 2024	CARBOMER HOMOPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED)	TOPICAL	LOTION		43	mg	R
1360	Q4 2023	CITRIC ACID MONOHYDRATE	TOPICAL	GEL	0.56 %w/w			R
1360	Q1 2024	CITRIC ACID MONOHYDRATE	TOPICAL	GEL		1	mg	R
1871	Q4 2023	DIETHYL SEBACATE	TOPICAL	LOTION	2.97 %w/w			R
1871	Q1 2024	DIETHYL SEBACATE	TOPICAL	LOTION		212	mg	R
2130	Q4 2023	EDETATE DISODIUM	TOPICAL	LOTION	0.12 %w/v			R
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Special Considerations

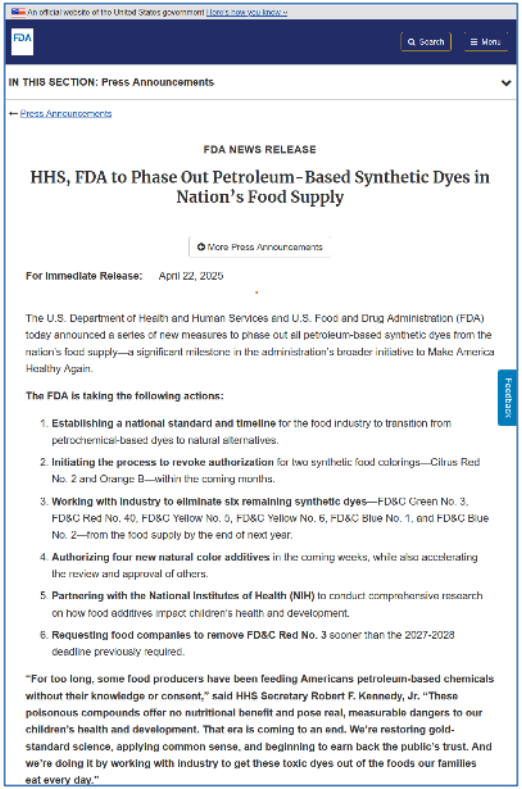
Red Dye No. 3

(also known as Erythrosine)

FD&C Red Dye No. 3 (Erythrosine)

- FDA FRN was posted on January 15, 2025
  - FDA revised 21 CFR color additive regulations to remove Red No. 3, and drug manufacturers have until January 18, 2028, to remove this color additive.
  - FDA has taken appropriate actions to address this ban
    - Red No. 3 and Erythrosine are no longer listed in the IID
  - Resources:
    - FDA to Revoke Authorization for the Use of Red No. 3 in Food and Ingested Drugs
    - Federal Register :: Public Inspection: Petition: Color Additive; Center for Science in the Public Interest, et al.;
    - Request to Revoke Color Additive Listing for Use of FD and C Red No. 3 in Food and Ingested Drugs

Considerations of Additional Color Additives



IN THIS SECTION: Press Announcements

← Press Announcements

FDA NEWS RELEASE

HHS, FDA to Phase Out Petroleum-Based Synthetic Dyes in Nation's Food Supply

More Press Announcements

For Immediate Release: April 22, 2025

The U.S. Department of Health and Human Services and U.S. Food and Drug Administration (FDA) today announced a series of new measures to phase out all petroleum-based synthetic dyes from the nation's food supply—a significant milestone in the administration's broader initiative to Make America Healthy Again.

The FDA is taking the following actions:

1. **Establishing a national standard and timeline** for the food industry to transition from petrochemical-based dyes to natural alternatives.
2. **Initiating the process to revoke authorization** for two synthetic food colorings—Citrus Red No. 2 and Orange B—within the coming months.
3. **Working with industry to eliminate six remaining synthetic dyes**—FD&C Green No. 3, FD&C Red No. 40, FD&C Yellow No. 5, FD&C Yellow No. 6, FD&C Blue No. 1, and FD&C Blue No. 2—from the food supply by the end of next year.
4. **Authorizing four new natural color additives** in the coming weeks, while also accelerating the review and approval of others.
5. **Partnering with the National Institutes of Health (NIH)** to conduct comprehensive research on how food additives impact children's health and development.
6. **Requesting food companies to remove FD&C Red No. 3** sooner than the 2027-2028 deadline previously required.

"For too long, some food producers have been feeding Americans petroleum-based chemicals without their knowledge or consent," said HHS Secretary Robert F. Kennedy, Jr. "These poisonous compounds offer no nutritional benefit and pose real, measurable dangers to our children's health and development. That era is coming to an end. We're restoring gold-standard science, applying common sense, and beginning to earn back the public's trust. And we're doing it by working with industry to get these toxic dyes out of the foods our families eat every day."

https://www.fda.gov/news-events/press-announcements/hhs-fda-phase-out-petroleum-based-synthetic-dyes-nations-food-supply

IN THIS SECTION: Press Announcements

← Press Announcements

FDA NEWS RELEASE

FDA Approves Three Food Colors from Natural Sources

More Press Announcements

For Immediate Release: May 09, 2025

The U.S. Food and Drug Administration today announced it granted three new color additive petitions that will expand the palette of available colors from natural sources for manufacturers to safely use in food.

The FDA is in line with U.S. Department of Health and Human Services Secretary Robert F. Kennedy Jr.'s priority to phase out petroleum-based dyes in the nation's food supply as part of the administration's broader initiative to Make America Healthy Again.

"Today we take a major step to Make America Healthy Again," said HHS Secretary Kennedy. "For too long, our food system has relied on synthetic, petroleum-based dyes that offer no nutritional value and pose unnecessary health risks. We're removing these dyes and approving safe, natural alternatives—to protect families and support healthier choices."

Since the HHS and FDA announcement last month during a press conference at HHS on petroleum-based food dyes, more U.S. food manufacturers have committed to removing them within the FDA's set time frame of the end of next year.

"On April 22, I said the FDA would soon approve several new color additives and would accelerate our review of others. I'm pleased to report that promises made, have been promises kept," said FDA Commissioner Martin A. Makary, M.D., M.P.H. "FDA staff have been moving quickly to expedite the publication of these decisions, underscoring our serious intent to transition away from petroleum-based dyes in the food supply and provide new colors from natural sources."

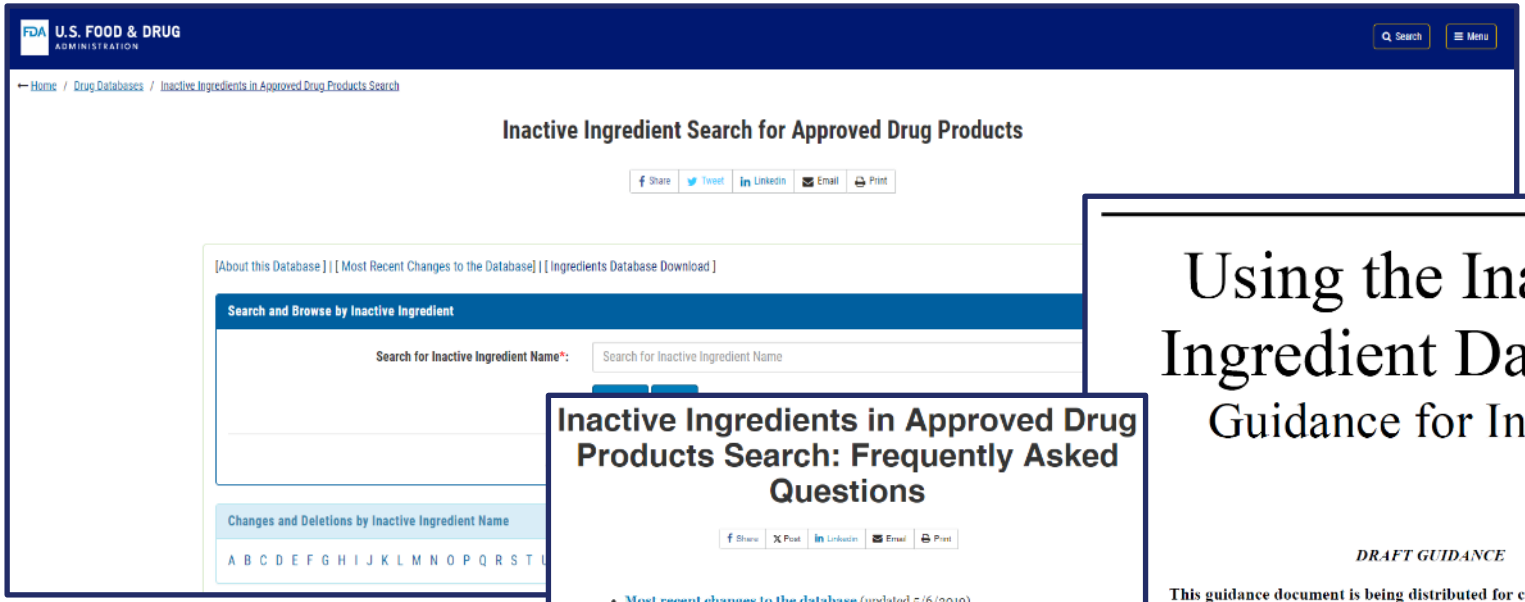
The color additive petitions approved today are for:

- Galdieria extract blue, a blue color derived from the unicellular red algae Galdieria sulphuraria. The FDA has approved the color additive for use in nonalcoholic beverages and beverage bases, fruit drinks, fruit smoothies, fruit juices, vegetable juices, dairy-based smoothies, milk shakes and flavored milks, yogurt drinks, milk-based meal replacement and nutritional beverages, breakfast cereal coatings, hard candy, soft candy and chewing gum, flavored frostings, ice cream and frozen dairy desserts, frozen fruits, water ices and popsicles, gelatin desserts, puddings and custards, and whipped cream, yogurt, frozen or liquid creamers (including non-dairy alternatives), and whipped toppings (including non-dairy alternatives). The petition was submitted by the French company Fermentalg.

https://www.fda.gov/news-events/press-announcements/fda-approves-three-food-colors-natural-sources

Helpful Resources

Helpful Resources



[Using the Inactive Ingredient Database Guidance for Industry | FDA]

[Inactive Ingredients in Approved Drug Products Search: Frequently Asked Questions]

IID Mailbox & Contact Information

Questions to the IID Mailbox

Ask us! We want to hear from you!

- ✓ Questions about changes in the IID listings and reports of error
- ✓ Requests for clarification of units or excipient names
- ✓ General inquiries only

We won't be able to provide an answer to…

- × Questions that may disclose proprietary information, e.g.,
  - × What NDA/ANDA a specific record belongs to
  - × Reference listed drug formulation
- × Acceptability of proposed excipient levels

Contact Information

- Questions and concerns about IID entries, send to IIDUpdate@fda.hhs.gov
- Nomenclature corrections, questions about excipient names, and UNII requests, send to FDA-SRS@fda.hhs.gov
- Application-specific questions related to the use of excipients in generic products under development should be submitted through the Controlled Correspondence pathway (https://www.fda.gov/media/164111/download)

FOOD AND DRUG ADMINISTRATION

CDER's Office of Generic Drugs

Office of Bioequivalence IID Team & Review Staff

CDER's Office of Pharmaceutical Quality

FDA's Office of Business Informatics

CDER's Office of Communications