

ANA MASTERS OF ADVERTISING LAW CONFERENCE

REGULATORY ENFORCEMENT: WHAT ADVERTISERS AND AGENCIES NEED TO KNOW

April 23, 2026

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GLP-1 DRUGS, COMPOUNDING & WEIGHT-LOSS MARKETING

FDA's Enforcement Focus



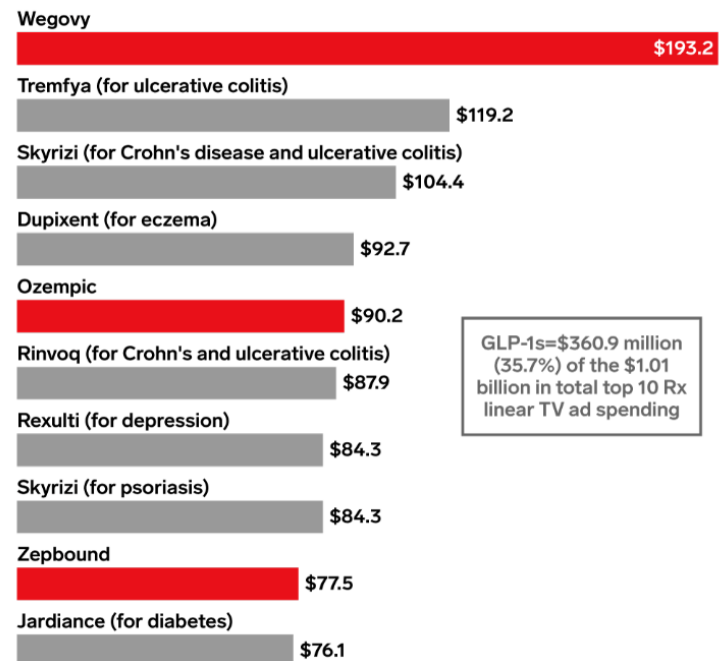
What Are GLP-1 Drugs and Why Does This Matter?

What Are GLP-1 Drugs?

- GLP-1 receptor agonists (glucagon-like peptide-1) are FDA-approved prescription drugs for Type 2 diabetes and obesity management
- **Ozempic** and **Wegovy** (semaglutide) and **Mounjaro** and **Zepbound** (tirzepatide)
- Among the most-prescribed and most-advertised drugs in the U.S. as of 2024–2025
- First half of 2025, GLP-1 drugs accounted for over 35% of all top prescription TV ad spending (~\$360 million)

GLP-1 Meds Accounted for More Than a Third of the Top 10 Rx TV Ad Spending in H1 2025

millions in US linear TV ad spending, by medication brand, H1 2025



GLP-1s=\$360.9 million (35.7%) of the \$1.01 billion in total top 10 Rx linear TV ad spending

Note: estimated linear TV ad spend
Source: iSpot.tv, July 1, 2025

353376

EMARKETER

Source: EMARKETER (Aug. 2025)

What Are GLP-1 Drugs and Why Does This Matter?

The Drug Shortage

- While a drug is on the shortage list, **federal law temporarily permits compounding pharmacies (503A or 503B Outsourcing facility)** to produce copies of that drug despite brand-name exclusivity.
- Created a massive, fast-moving market for **compounded semaglutide and tirzepatide**.
- Compounded versions were aggressively marketed through **telehealth platforms** and **direct-to-consumer digital advertising**.



Regulatory Development: The Shortage Designation Ends

FDA Removes GLP-1 Drugs from the Shortage List

October 2024 (reaffirmed December 2024): FDA determined the shortage of **tirzepatide** (Mounjaro/Zepbound) was resolved; compounding no longer broadly permitted.

February 2025: FDA determined the shortage of **semaglutide** (Ozempic/Wegovy) was resolved; same consequence.

Once a drug is removed from the shortage list, **503A and 503B compounding exemptions no longer apply.**

Compounding pharmacies had a **transition period** to wind down production and sales, largely to avoid unnecessary disruption to patient treatment.

Regulatory Development: The Shortage Designation Ends

But Marketing Continued . . .

- Many companies continued to market and sell compounded GLP-1 products due to FDA's leniency in enforcement.
- Some compounding pharmacies utilized **FDA's 503A "patient-specific" exception** making customized versions for patients, commonly using the addition of vitamin B-12 to the GLP-1.
- Some pivoted to marketing "**salt forms**" (e.g., semaglutide sodium, semaglutide acetate) and claiming these were distinct compounds not subject to the shortage-list restrictions.
 - FDA issued guidance rejecting this position: **salt forms are not meaningfully different** from the approved drug.



FDA Clarifies GLP-1 Policy: 503A Pharmacy Rules (April 1, 2026)

503A Pharmacies

- **Essentially-copy prohibition is in full effect.** FDA considers a compounded product to be *an essentially-copy* if it (i) shares the same Active Pharmaceutical Ingredient (“API”) (e.g., tirzepatide), (ii) **the same route of administration (e.g., injectable or pill)**, and (iii) the same, similar, or easily substitutable dosage strength as an FDA-approved product (Ozempic or Wegovy).
- **Four-prescription monthly compounding limit for Essential-Copy.** A 503A compounder can fill a maximum of **four (4)** or fewer prescriptions per calendar month for a particular essentially-copy compound.
 - Prescriptions supported by a physician’s documented 'significant difference' determination do not count toward this monthly limit.
- **Personalized products loophole eliminated.** FDA is clear that a compounded product combining semaglutide API with another ingredient (e.g., vitamin B12/cyanocobalamin) **will be treated as essentially a copy when the route of administration is the same (e.g., injectable)** and the amounts of each API dosage are within 10% of the respective commercially available strengths.
- **Cost is not a recognized clinical need.** Cost and convenience are not recognized reasons for ordering a compounded product.

FDA Clarifies GLP-1 Policy: 503A Compliance Implications

503A Pharmacy Compliance Implications

- Patient-specific compounding must be supported by an individualized, medically documented prescription prior to compounding.
- Pharmacies will need to track prescription volumes.
- Pharmacies may make only 4 essential copies (e.g., an injectable product with the Semaglutide API and vitamin B-12).
 - All other compounding beyond the 4 allowed essential copies must have appropriate documentation for the patient's significant risk difference (e.g. allergy or other issue necessitating a different route of administration).
- Patient prescriptions must affirmatively reflect the prescriber's significant-difference determination (e.g., patient has allergy to “x” in the brand product).
 - Pharmacies will likely begin to more tightly monitor this information prior to compounding.
- State board of pharmacies may conduct audits to verify compliance.

FDA clarifies GLP-1 policy (April 1, 2026)

503B Outsourcing Facilities:

- Cannot compound using bulk drug substances (API) unless on the 503B bulks list or the drug is on FDA's shortage list
- **Semaglutide and tirzepatide are not on the bulks list or shortage list**
- Prohibited from compounding essentially copies of approved GLP-1 drugs

Impact on 503B Patient-Specific Compounding:

- Patient-specific prescriptions do not override 503B restrictions: 503B facilities generally cannot compound these GLP-1 products
- Facilities should transition routine or bulk GLP-1 production

Key Enforcement Actions: FDA Warning Letters & Telehealth Marketing

• FDA's Warning Letter Campaign

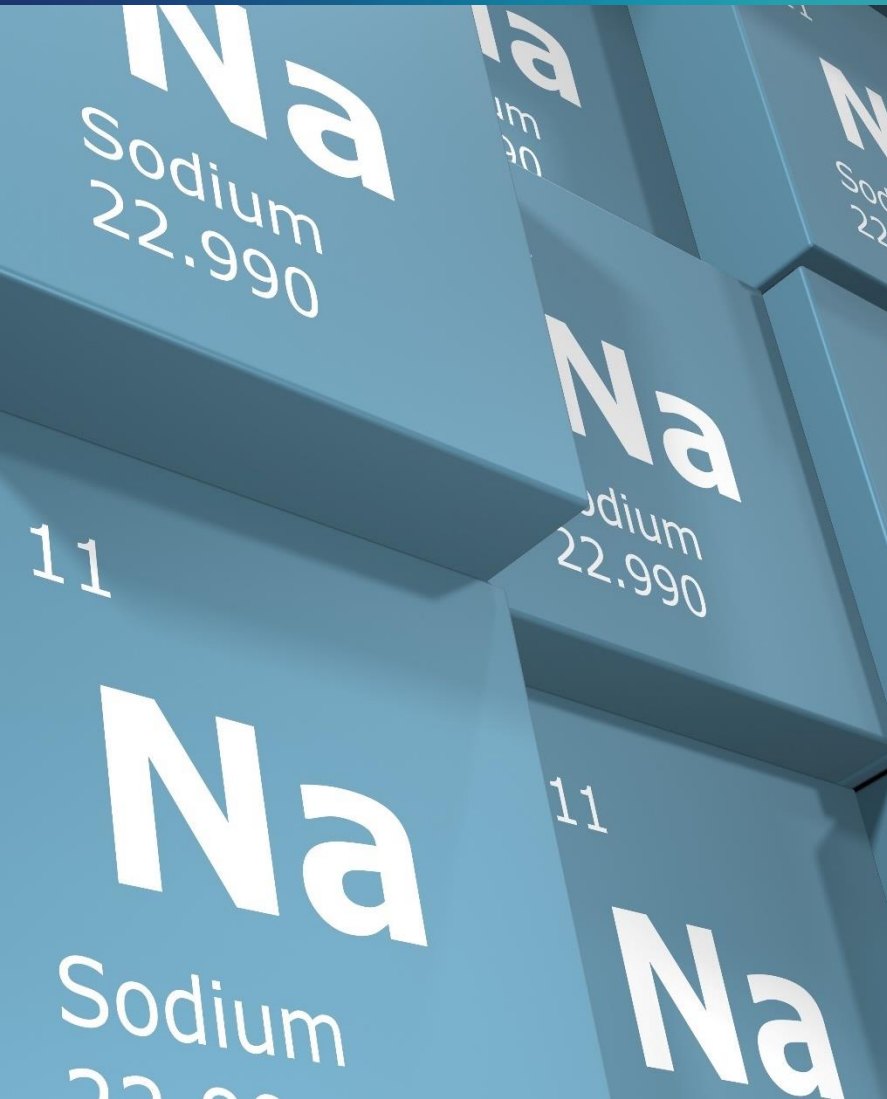
- FDA has issued **multiple warning letters** to compounding pharmacies, outsourcing facilities, and **telehealth companies**
- The **entire marketing and prescribing pipeline** is under review
- Targeted misleading claims about same APIs, cost, convenience, and efficacy relative to branded alternatives



Key Issues

- Marketing compounded GLP-1 drugs after the shortage designation ended
- Making **unsubstantiated efficacy claims** (e.g., "just as effective as Ozempic")
- Failing to include **required risk information and fair balance**
- Promoting unapproved compounds (including salt forms) as if FDA-approved
- Failing to **document patient-specific clinical differences** for "customized" versions (e.g., allergies, unique needs)
- Targeting consumers via **social media and digital advertising** with misleading claims

Practical Implications for Advertisers & Agencies



If You Market GLP-1 Products:

- **Branded GLP-1 drugs and compounded versions are governed by different rules**
- **Any compounded GLP-1 advertising is now presumptively high-risk**
- **Salt form products (semaglutide sodium, semaglutide acetate) are not a safe harbor**
- **Patient-specific versions** must be accompanied by a valid prescription order for an identified individual patient
- **Telehealth marketing** for GLP-1-adjacent services warrants heightened review

Practical Implications for Advertisers & Agencies

Adjacent Weight-Loss Product Considerations:

- FDA is actively scrutinizing **weight-loss supplement and wellness product claims** that exploit consumer awareness of GLP-1 drugs
- Claims that a product works "like Ozempic" or has "GLP-1 effects" require **robust scientific substantiation** and risk FDA enforcement as implied disease claims
- Review all influencer and social media content for **undisclosed risk information** and misleading comparative claims



Key Enforcement Trend: GLP-1 Adjacent Supplement Claims



The "GLP-1 Effect" Supplement Market – FDA's Emerging Focus

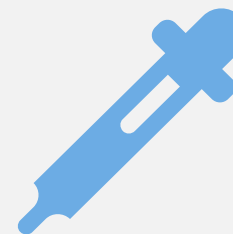
A market for supplements claiming to **naturally boost GLP-1 levels** or mimic GLP-1 drug effects has emerged in the wake of Ozempic/Wegovy's cultural prominence

Common claims in this space

- "Activates your body's natural GLP-1 response"
- "Works like Ozempic – without the prescription"
- "Supports GLP-1 hormone levels for natural weight management"

FDA's position: claims referencing **GLP-1 levels in the context of weight loss or blood sugar management are implied disease claims** – not permissible structure/function claims for dietary supplements

Enforcement risk: Products making these claims may be regulated as **unapproved new drugs**



Key Principle:

A product's legal classification follows its **intended use** as expressed through labeling and advertising – not its formulation.

A supplement that is advertised as having similar effects to a drug **becomes a drug** under FDA's regulatory framework.

FDA Warning Letter Language

"Your products are drugs . . . because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or intended to affect the structure or function of the body.

Examples from your product labeling, including on your website, that provide evidence of the intended use (as defined in 21 CFR 201.128) of these products as drugs include . . ."

THE "MAHA" AGENDA

FDA's Sweeping Actions on Food Additives, Artificial Dyes & the GRAS Process: What It Means for Advertisers

Background: What Is the MAHA Initiative?

Make America Healthy Again (MAHA)

- Trump Administration health policy initiative targeting **ultra-processed foods, food additives, and synthetic ingredients** in the American food supply
- Led by **HHS Secretary Robert F. Kennedy Jr.** and implemented through FDA, USDA, and other agencies
- Framed around the premise that **the U.S. food regulatory system has been insufficiently rigorous** in protecting consumers from potentially harmful additives
- Creates a political and regulatory environment in which **FDA has strong top-down pressure to act faster and more broadly** than it has historically

Background: What Is the MAHA Initiative?

The Delaney Clause — FDA's Legal Anchor

- The **Delaney Clause** (21 U.S.C. § 348(c)(3)(A); see also § 379e(b)(5)(B) for color additives) generally prohibits FDA from approving a food additive that has been found to **induce cancer in humans or animals**
- MAHA's initiative regarding food additives largely **mirrors** Delaney's standard
- The standard is treated as **absolute** — even a small cancer risk triggers the prohibition
- FDA cited the Delaney Clause as the legal basis for the **revocation of Red Dye No. 3** and certain other additives
- MAHA has renewed FDA's willingness to apply the Delaney Clause aggressively after decades of limited use

Key Regulatory Action: Red Dye No. 3 — Revocation Already in Effect

- **FDA Revokes Authorization for Red Dye No. 3 (FD&C Red No. 3 / Erythrosine)**
 - **Effective Date:** January 15, 2025
 - **Legal basis:** Delaney Clause: animal studies found the dye induces cancer
 - **Phase-out deadlines:**
 - **Food products:** Remove from all formulations by **January 15, 2027**
 - **Ingested drugs:** Remove by **January 18, 2028**
 - Existing inventory manufactured before the applicable compliance deadline may continue to be **sold through** those dates



Key Regulatory Action: FDA's April 2025 Announcement — The Six Remaining Dyes

FDA's April 22, 2025, Announcement

- FDA announced it is **initiating revocation proceedings** for:
 - **Citrus Red No. 2**
 - **Orange B**
- FDA announced it is **working with industry** to voluntarily eliminate **six remaining petroleum-derived synthetic dyes** by end of **2026**:
 - FD&C **Green No. 3** | **Red No. 40** | **Yellow No. 5** | **Yellow No. 6** | **Blue No. 1** | **Blue No. 2**
- FDA simultaneously **authorized four new natural color additives** and committed to accelerate review of additional natural alternatives

Key Regulatory Action: FDA's April 2025 Announcement — The Six Remaining Dyes

- **Post-Market Chemical Review List (August 2025 Update)**
 - FDA updated its post-market review list to include the **six remaining synthetic dyes** plus newly added chemicals such as:
 - **BHA | BHT | Azodicarbonamide | Lead** (as food contact substance impurity)
- **GRAS Process Reform**
 - **Secretary Kennedy** directed FDA to explore rulemaking to **eliminate the self-determined GRAS process**
 - Currently, companies can **self-determine** that an ingredient is "Generally Recognized As Safe" without formal FDA review or notice
 - Eliminating this pathway would require **manufacturers to submit mandatory notice to the FDA, subject to FDA review and potential objection** — potentially a significant burden on innovation and reformulation

The State-Level Patchwork: Warning Labels & Outright Bans

West Virginia

HB2354:

State-wide ban on sale of foods and school meal ban on seven synthetic dyes

Preliminary injunction obtained Dec. 2025

(vagueness grounds — International Association of Color Manufacturers challenge)

School meal ban on dyes remains in place, but statewide retail ban subject to injunction

California

AB418:

(effective January 1, 2027) bans four food additives from being manufactured, sold or distributed in state

AB2316:

(effective July 1, 2025 for school meals) ban on six synthetic dyes in public schools

Arkansas

Act 622

(enacted 2025) partial statewide ban on 3 food additives

The State-Level Patchwork: Warning Labels & Outright Bans

- **Industry Legal Challenge — Texas SB 25**

- The most contested part of SB 25 is a mandate for a specific label on food products in TX that contain any of 44 listed ingredients as **“this product contains an ingredient that is not recommended for human consumption by the appropriate authority in Australia, Canada, the European Union or United Kingdom”**
- Filed: **December 2025** by American Beverage Association, Consumer Brands Association, National Confectioners Association, and the Food Industry Association
- **Three grounds:**
 - a. **First Amendment** — compels businesses to make inaccurate and misleading statements
 - b. **Federal preemption** — conflicts with FDA's exclusive authority to regulate food labeling
 - c. **Void for vagueness** — insufficient clarity on which products are covered speech that fails scrutiny.

The proposed controversial food warning label requirement was scheduled to apply to packaging created on or after January 1, 2027.

A Texas federal court issued a preliminary injunction on February 11, 2026, blocking enforcement of the warning label while the case proceeds.

As of March 2026, the **Texas Attorney General is expected to appeal this ruling to the 5th Circuit.**

Industry Response: Brands Are Moving Ahead of Regulators

Voluntary Reformulation Commitments by Major Brands

- **FDA maintains a webpage that tracks voluntary industry reforms:**
 - **Kraft Heinz** — Pledged to stop launching new products with synthetic dyes and reformulate existing lines by the end of 2027.
 - **General Mills** — Eliminating certified color additives from full U.S. retail portfolio by the end of 2027
 - **PepsiCo** — New line of Cheetos® and Doritos® products will be made with no artificial flavors or dyes
 - **Nestlé S.A.** — Eliminating certified color additives in U.S. food and beverage portfolio by mid-2026
 - **Walmart** — Removing certified color additives and more than 30 other ingredients – like certain preservatives, artificial sweeteners, and fat substitutes – from its private brand foods by January 2027

Below is a summary of industry commitments, as of December 12, 2025. Companies can contact the FDA's [Food and Cosmetic Information Center](#) to ensure their commitments are reflected on this page.

Industry Tracker: Pledges to Remove Petroleum-Based Food Dyes

Search: Export Excel

Company	Product(s) or Brand(s) Affected	Planned Changes	Status
American Bakers Association	ABA Member List	<ul style="list-style-type: none"> Eliminate the use of certified FD&C colors in all baked goods provided to K-12 schools through the National School Breakfast, Lunch, and Competitive Foods Programs by the beginning of the 2026-2027 school year. 	In progress
Campbell's	Lance Crackers, V8 Splash; regional snacks brands such as Jay's, O-Ke-Doke, Tom's; cookie brands such as Archway, Stella D'oro	<ul style="list-style-type: none"> Will no longer produce any food or beverages with FD&C colors by the second half of the 2026 fiscal year 	In Progress
Conagra Brands, Inc.	Birds Eye®, Duncan Hines®, Marie Callender's®, Slim Jim®	<ul style="list-style-type: none"> Eliminate of certified color additives from U.S. frozen product portfolio by the end of 2025. Will not sell products with certified color additives to K-12 schools by the beginning of the 2026-2027 school year. Discontinue the use of certified color additives across U.S. retail portfolio by the end of 2027. 	In progress
Consumer Brands Association (CBA)	Member List	<ul style="list-style-type: none"> Stop using certified color additives for school meals by 2026 school year. Encourage America's food and beverage makers to stop manufacturing with certified color additives in products by December 31, 2027. 	In progress
Danone U.S.	Light + Fit Greek, YoCrunch	<ul style="list-style-type: none"> Eliminate certified color additives from U.S. portfolio. 	In progress
General Mills, Inc.	Betty Crocker®, Bisquick®, Cheer® Cereal, Cinnamon Toast Crunch®, Häagen-Dazs™, Pillsbury®, Progresso®, Trix®	<ul style="list-style-type: none"> Eliminate certified color additives from all U.S. cereals and all K-12 school foods by summer 2026. Eliminate certified color additives from full U.S. retail portfolio by the end of 2027. 	In progress
Grupo Bimbo, S.A.B. de C.V.	ARNOLD®, Little Bites®, THOMAS®	<ul style="list-style-type: none"> Remove certified colors from the entire portfolio by the end of 2026. 	In progress
In-N-Out Burger®	Strawberry Shakes and Signature Pink Lemonade	<ul style="list-style-type: none"> Eliminated certified color additives from Strawberry Shakes and Signature Pink Lemonade. 	Complete

Source: <https://www.fda.gov/food/color-additives-information-consumers/tracking-food-industry-pledges-remove-petroleum-based-food-dyes>

Industry Response: Brands Are Moving Ahead of Regulators

What This Creates for Advertisers:

- A **competitive advertising race** to claim "no artificial colors," "made with natural colors," and similar clean-label messaging
- Consumer expectations are increasingly shaped by these public commitments
- On February 5, 2026, the FDA announced it intends to **exercise enforcement discretion** regarding the use of certain voluntary labeling claims on foods that **do not contain FD&C certified colors**.
- FDA does not intend to take enforcement action against manufacturers who use phrases like "**made without artificial food colors**" or "**no artificial color**" on products that don't use any of the synthetic dyes listed in **21 CFR Part 74**

Important Compliance Considerations

- **Flexibility**

- Gives manufacturers **increased flexibility to make “no artificial colors” claims on product labels** even when colorants have been added to the product, so long as synthetic petroleum-based colors have been replaced with **FDA-approved natural alternatives**

- **Risks**

- Although the FDA has signaled that it will not enforce **Section 403(a)(1)** for labeling claims covered under the February guidance, Section 403(a)(1) **still prohibits labeling that is false or misleading**

- **Federal enforcement discretion does not preempt stricter state laws**

- FDA’s policy does not override more stringent state consumer protection laws like those in California and West Virginia

- **Litigation Risks Still Remain**

- State attorneys general or private litigants may pursue enforcement actions under state statutes
- Claims like “no artificial colors” could be **challenged as misleading**

- **The Plaintiff's Bar Is Watching**

- Consumer class actions targeting food advertising claims remain active
- Plaintiff lawyers will compare **product labels** against advertising claims

Key lesson:

Have strong processes to review labeling and closely track state-level consumer protection laws

Alcohol and Tobacco Tax and Trade Bureau: Color Additives

Additives in Alcohol: Current Rules

The TTB defers to FDA decisions on food and beverage additives.

- Use of additives is governed by the Food, Drug, & Cosmetic Act.
 - The FDA must provide pre-market approval for use of additives.
 - If the FDA approves the additive, it will issue a regulation identifying the approved use(s).
 - Alcohol manufacturers may only use additives approved for (1) general use in food or (2) specific use in alcohol.
- The TTB generally requires:
 - Pre-market approval of formulas containing color additives (including for changes to existing formulations).
 - Disclosure of color additives on beverage labels.

Additives in Alcohol: Recent FDA Actions

- The FDA revoked authorization of Brominated Vegetable Oil (in 2024) and Red No. 3 dye (in 2025).
 - **August 2, 2025:** Compliance date to remove BVO-containing products from shelves.
 - **January 15, 2027:** Compliance date to remove Red No. 3-containing products from shelves.
 - The FDA plans to revoke authorization for the remaining certified color additives by the end of 2027.
- In 2026, the FDA approved two additional “naturally-derived” color additives for general use in alcoholic beverages:
 - **Spirolina extract** (previously approved for beverages with less than 20% ABV).
 - **Beetroot red** (betanin)
 - Effective date has been paused pending evaluation of objections.

TTB: AI in Alcohol Advertising

AI in Alcohol Advertising: Current Governance

- Alcohol advertising governed by:
 - **Federal Alcohol Administration Act and TTB regulations** regarding the labeling and advertising of "distilled spirits, wines, and malt beverage products."
 - **Food, Drug, and Cosmetics Act and FDA regulations** regarding labeling and advertising of beverages that are outside TTB authority (e.g. hard seltzers, ciders, and kombucha).
 - **Federal Trade Commission Act and FTC regulations** regarding false and deceptive advertising practices.
- No AI-specific laws or regulations governing advertisements, but the 2025 Executive Order promotes creation of a national AI policy framework.



AI in Alcohol Advertising: Recent Guidance



- In March 2026, the TTB published tips for using AI into alcohol advertisements:
 - **Product characteristics:** advertisements should not mislead consumers as to the product’s appearance, color, or characteristics.
 - **Health effects:** advertisements must not include any false or misleading statements on the health effects of alcohol or alcohol consumption.
 - **Accuracy of depiction:** AI-generated product labels must be accurate reproductions of approved labels.
 - **Seek pre-clearance review:** If in doubt, the TTB Market Compliance Office provides free pre-clearance review of advertisements.

TTB Rulemaking: Allergens & Nutrition Facts Labeling

Allergens & Nutrition Facts Labeling: Current Rules

- **Allergens:**

- The FDA **requires** disclosure of major food allergens on labels.
- The TTB allows for **voluntary** disclosure of major food allergens.
 - If choosing to disclose, must include *all* major allergens.

- **Nutrition Facts:**

- The FDA **requires** nutrition and ingredient labels on most prepared foods (including alcoholic beverages not regulated under the TTB).
- The TTB allows for **voluntary** inclusion of such fact statements.
 - Nutrition fact statements must ascribe to certain tolerances (*i.e.* how much a label may over or understate nutrient content).
 - FDA-certified additives *must* be disclosed (*e.g.* aspartame, Yellow No. 6)

Allergens & Nutrition Facts Labeling: Proposed Rules

Allergen Labeling Rule

- Would require disclosure of major food allergens used in alcoholic beverage production.
 - Proposed rule defers to FDA allergen definitions, disclosure thresholds, and labelling exceptions.
- The TTB also sought public comment on:
 - Format of allergen label and suggested alternatives;
 - Whether other mandatory disclosures (*i.e.* additives) should be combined with major allergen disclosures;
 - Whether the TTB should require allergen advisory labeling (*e.g.* "*May contain [major food allergen(s)]*");
 - Effect of proposed rule on consumers and the alcoholic beverage marketplace.

Allergens & Nutrition Facts Labeling: Proposed Rules

- **Nutrition Facts Labeling Rule**

- Would require an "Alcohol facts" statement addressing serving size; servings per container; alcohol content; and the amount of ethyl alcohol, calories, carbohydrates, fat, and protein per serving.
- The TTB also sought public comment on:
 - Format, content, and delivery method of Facts statement (including consistency with the FDA);
 - Threshold for disclosure requirements and tolerances;
 - Whether inclusion of other micronutrients would be useful or misleading;
 - Effect of proposed rule on consumers and the alcoholic beverage marketplace.



Allergens & Nutrition Facts Labeling: Current Status

- Comment period for both rules closed in **April 2025**
- If adopted, both rules would have a **five-year** implementation period
- Proposed rules seek to harmonize any future rule with current FDA labeling requirements.



Federal Trade Commission: FTC Announces 5-year Strategic Plan

FTC Strategic Plan



- The Plan was published in **April 2026** for **2026-2030**.
- The Plan identified three key **strategic goals**:
 1. Protect Americans from unfair or deceptive acts or practices in the marketplace.
 2. Protect Americans from unfair methods of competition, prevent illegal monopolies, and promote competition.
 3. Protect Americans and maximize mission outcomes through operational excellence and efficiency.

Achieving the 5-Year Plan

- **Goal #1** focuses on **identifying** consumer protection violations, **enforcing** consumer protection laws, and **educating** consumers and businesses on fraudulent and illegal practices.
— Children’s online safety is a particular area of concern.
- **Goal #2** focuses on **investigating** and **preventing** anticompetitive mergers, **educating** businesses on competition-promoting practices, and **advocating** for pro-competitive laws and regulation.
- **Goal #3** focuses on **optimizing** available administrative resources and information management infrastructure, and **training** FTC staff.

FTC: Privacy, COPPA, and Age Verification Laws

Privacy as an FTC Priority

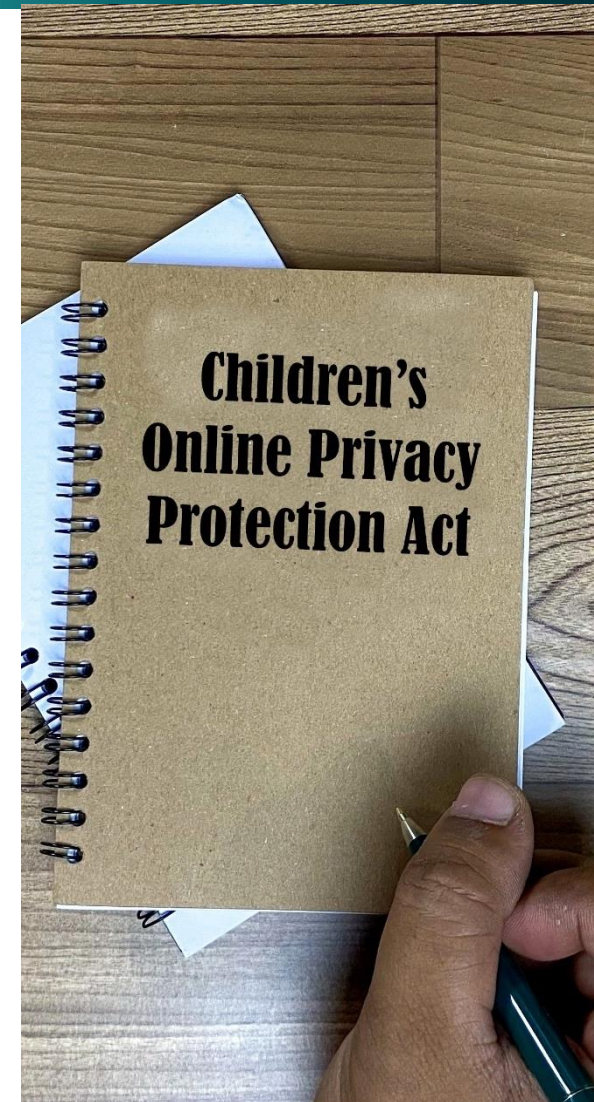


Enforcing privacy protections is a central FTC concern.

- In March 2026, the FTC sued **OkCupid** and **Match Group Americas** for unlawfully sharing users' personal information.
 - The FTC alleges OkCupid shared **3 million users'** personal data with an unrelated third-party, with no use restrictions.
 - The FTC also alleges OkCupid and Match concealed their actions when the third-party's data collection became public.
- In January 2026, the FTC finalized an order against **General Motors** for unlawfully collecting and selling consumer data.
 - The order prohibited the sale of consumer data for 5 years.
 - The order also required GM obtain express consent to collect data and provide multiple avenues for consumers to prevent data collection or sale.

Children's Online Privacy: Current Rules

- **Children's Online Privacy Protection Act (COPPA):**
 - Prohibits websites and online service providers from collecting children's (under 13) personal information without parental notice and consent.
 - Applies to providers with **actual knowledge** that they are collecting children's personal information.
 - Parental notice must include **what** information is collected, **how** it's used, and **disclosure practices**.
 - Providers must maintain reasonable information protection procedures.
- The FTC regulates and enforces COPPA under the **COPPA Rule**.



Children's Online Privacy: COPPA 2.0 & KOSA

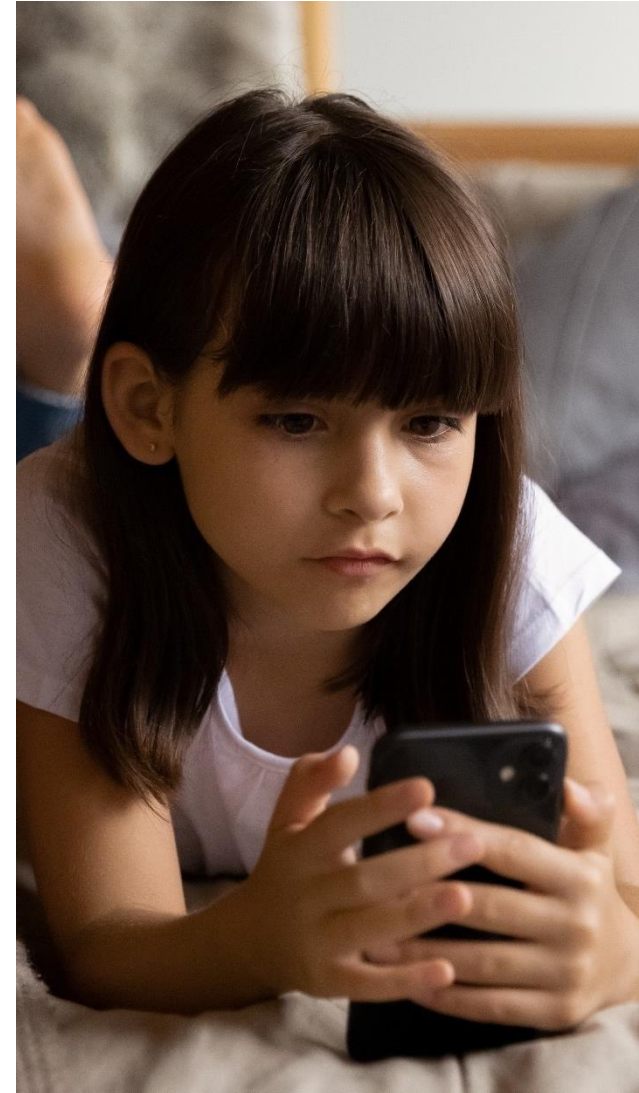


Two bills currently moving through Congress.

- **COPPA 2.0** expands COPPA protections and requirements.
 - Applies to children under 17.
 - Lowers knowledge requirement to “knowledge fairly implied on basis of objective circumstances.”
 - Imposes additional collection, use, storage, and transfer requirements (including creating a “right to delete”).
 - Allows states to legislate stricter protections.

Children's Online Privacy: COPPA 2.0 & KOSA

- **Kids Online Safety Act (KOSA)** requires online platforms to “prevent and mitigate” certain harms to minors in their platform design.
 - Applies to children under 17.
 - “Harms” include sexual exploitation, compulsive internet use, drugs, and financial harms caused by deceptive practices that violate the FTC Act.
 - Requires platforms to provide safeguards that limit interaction and data collection for minor visitors, and to restrict design features that encourage compulsive use.



Children's Online Privacy: Disney & Youtube

The FTC is continuing to prioritize COPPA enforcement.

- In December 2025, a federal judge approved a \$10 million settlement with **Disney** regarding YouTube channel designations.
 - Disney's channel-level audience designations led to kid-targeted content getting marked "not for kids."
 - Result: the channels improperly collected children's data and autoplayed other "not for kids" content.
- The FTC used settlement to remind other content creators to be aware of their audience designations on both channels *and* videos.



Children's Online Privacy: New Policy Statement

The **COPPA Rule** forbids collection of children's data without parental notice and consent.

- Compliance with state age verification laws often require providers to collect children's data for age verification purposes.
- In February 2026, the FTC announced it will not enforce the COPPA Rule against mixed or general audience websites that collect data for age verification purposes.
 - Providers may only collect and temporarily retain data for that limited purpose.
- The FTC also announced plans to amend the COPPA Rule to better address age verification mechanisms.

FTC: The Consumer Review Rule

What is the Consumer Review Rule?



- The **Consumer Review Rule (CRR)** became effective in October 2024.
- The Rule prohibits deceptive or misleading review practices, including:
 - Reviews that misrepresent to consumers whether a reviewer liked or used a product (including AI-generated reviews);
 - Incentivizing specific types of reviews (positive or negative);
 - Posting of insider reviews.

Consumer Review Rule: First Actions

- In December 2025, the FTC sent letters to 10 companies regarding their review practices.
 - The letters reminded them of their obligations under the CRR and warning them of consequences for noncompliance.
 - This appears to be the first enforcement action taken under the CRR.
- The letters were based on consumer complaints and company disclosures and were not a formal determination of CRR violation.



Consumer Reviews and AI: Rytr



- Also in December 2025, the FTC reopened and set aside a 2024 Consent Order against AI company **Rytr**.
 - Pre-CRR, the FTC alleged Rytr’s “review writing service” violated the FTC Act by enabling the creation of “false and deceptive online reviews.”
- The decision was made in response to President Trump’s AI Executive Order.
- The FTC stated the previous allegation and Consent Order were based on the *potential* for Rytr’s service to violate the FTC Act rather than on *actual* violations.
 - The new Order is not meant to indicate approval of AI-generated reviews.

FTC Deceptive Practices: Dark Patterns & Negative Options

Deceptive Practices: Dark Patterns & Negative Options

- **Dark Patterns** – Practices meant to trick consumers into buying products, sharing personal information, or signing up for subscriptions, including:
 - Making it difficult to cancel subscriptions or recurring charges;
 - Advertising attractive sales prices and burying key terms;
 - Using misleading language on consumer privacy settings.
- **Negative Options** – Sales practices that treat consumer silence or inaction as an affirmative consent to be charged (e.g. automatic renewals, free-to-pay conversions, or pre-notification subscriptions).
 - The **Negative Option Rule** prohibits negative options where they are based on deceptive practices, including dark patterns.
- Governed primarily by **ROSCA** and the **FTC Act**.

Deceptive Practices: Recent Settlements

- The FTC continues to prioritize enforcement actions against companies using dark patterns and deceptive negative option practices.
- The FTC has recently settled multiple claims against companies for such practices:
 - September 2025 – Settlement with **Chegg** for deceptive subscription billing and cancellation practices
 - December 2025:
 - **Instacart** settlement for deceptive pricing and advertising, inadequate disclosure of terms, and hiding refund options.
 - **Legion Media, LLC, et al.** settlement for enrolling consumers in subscription plans without consent.
 - **NextMed** final order for deceptive advertising, billing, review, and cancellation practices and undisclosed membership enrollment.

The logo for Chegg, featuring the word "Chegg" in a bold, orange, sans-serif font.The logo for Instacart, featuring a green leaf icon to the left of the word "instacart" in a bold, dark green, sans-serif font.

Deceptive Practices: Continued Enforcement

In January 2026, the FTC sued **JustAnswer LLC** for using deceptive subscription enrollment tactics.

- In March 2026, the FTC sent letters to **97 auto dealers** regarding deceptive pricing practices.
 - The letter warned auto dealers that advertised prices must reflect the total price, including all mandatory fees.
 - It also warned against other illegal pricing practices, including:
 - Advertising discounts not available to all consumers
 - Conditioning advertised prices on dealer financing; and
 - Conditioning advertised prices on purchasing additional items not included in the advertising.

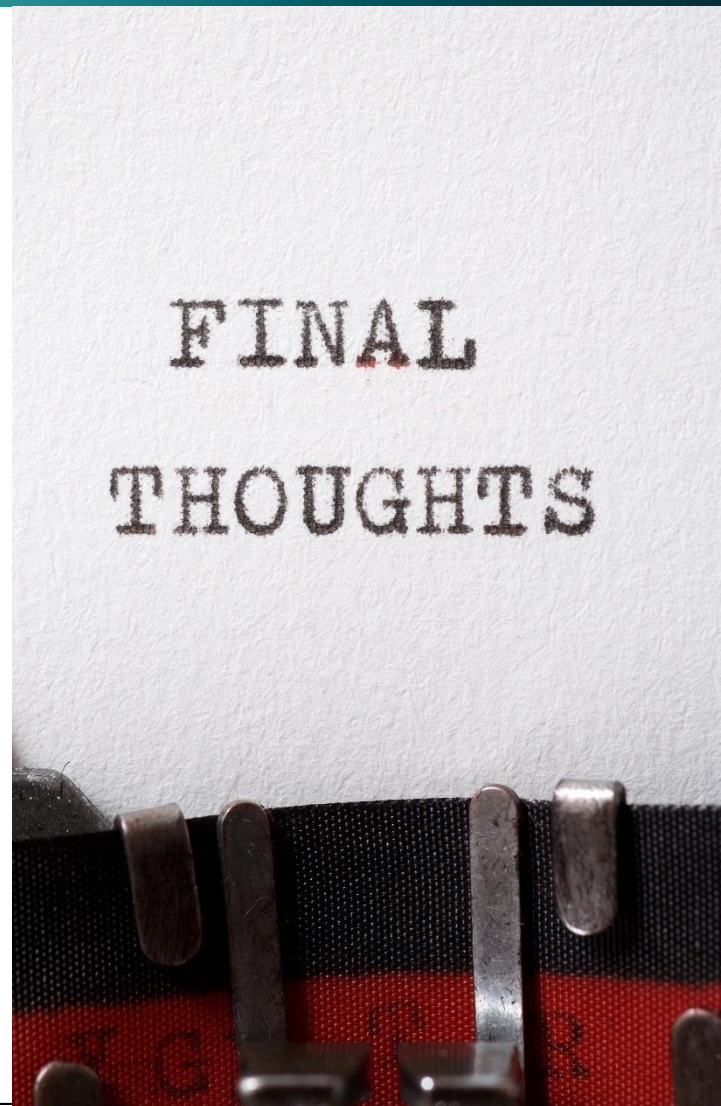


Deceptive Practices: Negative Option Notice of Proposed Rulemaking

- In 2024, a federal court vacated the Negative Option Rule's 2019 Amendments for failure to follow legal procedures.
 - The Amendments addressed modern subscription practices not covered by existing regulations (such as ROSCA).
- In March 2026, the FTC issued an **Advanced Notice of Proposed Rulemaking** and **Request for Public Comment** regarding new amendments to the Rule.
- The FTC sought input on matters including:
 - The substance of the 2019 Amendments and suggestions for alternatives;
 - Information on improper or deceptive negative option practices;
 - Empirical data on the use and misuse of negative options.
- The Comment Period closed on April 13.

FTC Final Thoughts and Takeaways

- Deceptive pricing and subscription practices remain a main enforcement priority.
- The FTC is continuing to evaluate how it addresses child privacy.
- The FTC is beginning to take action under the new Consumer Review Rule, notwithstanding the recent Rytr AI Order.



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