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THE FIELD GUIDES

VOLUME FOUR

HAIR CARE

Six questions for reading any personal-care label, and seven materials read against them.

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Question Zero — What kind of label am I holding?

Ask this before the other five. It decides which of them apply.

Not everything on a personal-care shelf is a cosmetic in law, and the difference is printed on the pack if you know what to look for. In the US, what a product legally *is* depends on what it is intended to do.

The three kinds

1 • Cosmetic. Intended to cleanse or beautify. One ingredient list, in descending order of weight, no percentages disclosed. The FDA does not pre-approve cosmetic products or ingredients — with one important exception, color additives, which matters for Question 1.

Moisturizers, most shampoos, lipstick, nail polish, deodorant, perfume.

2 • Cosmetic and drug. Intended to cleanse or beautify **and** to treat or prevent something or affect the body's structure or function. These carry both sets of obligations, and the label shows it.

The structural giveaway: under 21 CFR 701.3(d), a product that is both must identify the drug ingredients as "**Active Ingredients**" **first**, before the cosmetic ingredients are listed. So, the list is split in two: actives at the top with their **exact percentages stated**, then the inactive in ordinary descending order.

Examples the FDA gives directly: anti-dandruff shampoo, antiperspirant-deodorants, moisturizers and makeup sold with SPF claims. Also acne treatments and hand sanitizers.

The single cleanest illustration, and it's on one shelf: a deodorant is a cosmetic — it masks odour. An antiperspirant is a drug — it reduces sweating, which is affecting a function of the body. Same aisle, same format, two different legal categories and two different labels.

3 • True soap. A narrow legal category: consisting primarily of an alkali salt of fatty acids and making no claim beyond cleansing. Products meeting that definition are **not regulated by the FDA at all** — they fall to the Consumer Product Safety Commission, and they are not required to carry a cosmetic ingredient list.

Most things sold as "soap" today are not true soap in this sense; they are cosmetic cleansing bars, and they do carry a list.

If a cleansing bar has no ingredient list, this is usually why — not an oversight.

MATERIAL 07 — THE FLAGSHIP PROFILE

7. Minoxidil

INCI/CHEMICAL NAME Minoxidil · **FORMULA** $C_9H_{15}N_5O$ · **FUNCTION GROUP** OTC drug active (hair regrowth treatment)

Origin. The Upjohn Company developed minoxidil in the 1950s while looking for a treatment for stomach ulcers. Animal testing found it did nothing for ulcers at all — but researchers noticed it relaxed blood vessels, a vasodilator effect with an entirely different medical use. On the strength of that discovery, the FDA approved it in the 1970s as an *oral* tablet for severe high blood pressure, marketed as Loniten. Patients taking it for their blood pressure began reporting an unrelated side effect: hair growth. That observation was investigated over the following decade, and in August 1988 the FDA approved a topical version specifically for male pattern hair loss, under the name Rogaine — a drug that began as a failed ulcer treatment, succeeded as a blood pressure medication, and became a hair product because of what it did to people taking it for something else entirely.

Why it's classified as a drug — Question Zero, a second time in this series, with a new dimension. Minoxidil is regulated as an OTC drug, requiring Drug Establishment Registration and Drug Facts labeling — the same structural markers Question Zero already taught you to look for. Its path to that status is worth being precise about: unlike an ingredient-class OTC monograph (the kind that covers anti-dandruff actives), minoxidil's hair-growth indication required product-specific clinical trials and was approved through a New Drug Application, later reaching over-the-counter status via an FDA "Rx-to-OTC switch" — a different regulatory road to the same destination, not the same monograph process applied twice. What's new here beyond that: the approval doesn't just set one concentration limit, it sets **different limits for different declared populations**. The 2% solution is permitted for both men and women. The 5% solution and foam are permitted for men only — women are specifically excluded from that higher-concentration formulation. This is a different kind of split than the drug/cosmetic line Category C's flagship demonstrated: here, the same active ingredient, the same product category, and the same general purpose are still divided by regulation, based on a declared characteristic of the user rather than a claim on the pack.

What the label discloses, and what this guide doesn't add to it. The approved labeling requires continuous use to maintain results and states hair loss will resume if use stops — a disclosed usage instruction, not a claim this guide is making about how well the product works. The mechanism by which minoxidil affects hair growth is, per the sources reviewed for this profile, still not fully established even in the scientific literature describing an approved and widely used drug.

Elsewhere. Minoxidil's original approved use — as an oral antihypertensive — remains active, entirely separate from any cosmetic or hair-care context. It's also occasionally used in veterinary contexts, though topical formulations intended for humans carry specific warnings against use around animals, since minoxidil toxicity has been documented in cases of accidental pet exposure.

What the framework sees — Question Zero, extended. Check for a Drug Facts panel, exactly as Question Zero always instructs. But this material shows the check has a second layer worth running once you've confirmed a product is a drug: *which* concentration is permitted, and for whom. A 5% formulation marketed generally, without the men-only restriction made clear, is a mismatch between the product and its own approved labeling — the same kind of scope question that Volume Two's flagship colorant taught you to look for in a completely different context.

Start with the limit, not the promise.

The familiar limit opens this Part 3 too: an ingredient list cannot separate formulation cost from marketing cost. What's new to this category is a cost driver more specific than anything in Volume Three. That volume showed a drug-versus-cosmetic split creates its own compliance cost tier. This one shows something sharper: **two products can both be legitimate OTC drugs, with the identical active ingredient at the identical concentration, and still carry entirely different cost histories — because they reached the shelf by different regulatory roads, or because a patent protected one delivery format years longer than another.**

What this section does. Shows which of Volume Four's seven materials carry price information, explains how the NDA-versus-monograph distinction from Part 1 translates into real cost differences, introduces a genuinely new driver — patent protection that varies by product *format*, not just by active ingredient — and works through the four positionings on a shelf where salon-exclusive distribution adds a channel this series hasn't addressed before.

Which materials actually carry price information?

MATERIAL	PRICE INFO?	ON LABEL?	WHAT ACTUALLY DIFFERS
Minoxidil	Strongly — but through patent & format history	Yes — concentration disclosed, not regulatory history	Brand, generic, and format (solution vs. foam) carry very different prices for the identical active
Zinc Pyrithione	Barely	Yes	An ingredient-class monograph active; low barrier to entry keeps most products near a similar cost floor
PPD	Somewhat	Yes	The coal-tar-dye exemption keeps compliance costs low; salon-exclusive vs. retail distribution is a bigger price driver than the chemistry
Behentrimonium Chloride	Barely	Yes	Commodity conditioning agent, present across tiers
Rice Starch	Barely	Partly	Modified/esterified starches cost more but aren't always named separately
Hydrolyzed Keratin	Strongly, but invisibly	No	A thousand-fold molecular weight range and multiple source species, neither disclosed
Citric Acid	Barely	Yes	Commodity pH adjuster, present across virtually every tier

THE PATTERN

Hydrolyzed Keratin repeats the now-familiar shape — high price relevance, total label invisibility. Minoxidil breaks that pattern entirely: here, the price driver isn't even about the material's grade or source. It's about *when* a given formulation lost patent protection, and in what format.

Walkthrough 1 — Two OTC hair products, two roads to the same shelf

The situation. A shopper is comparing a minoxidil hair-regrowth treatment and an anti-dandruff shampoo, both sitting in the same "hair care — drug" section, both carrying visible Drug Facts panels.

Run the questions.

Q0 confirms both are drugs — that much is settled the moment a Drug Facts panel is found on each. But Part 1's distinction is worth applying here: the anti-dandruff shampoo's active, zinc pyrithione, is one of several actives named directly in a published ingredient-class monograph. Any manufacturer can use it at the monograph's specified concentration without conducting new trials — the safety finding already covers the whole category. The minoxidil product's approval history runs differently: its hair-growth indication required product-specific clinical trials under a New Drug Application, later reaching OTC availability through a switch.

What you now know. Both products are legitimately drugs, confirmed by the identical check — a Drug Facts panel. But *why* each is a drug, and which regulatory road it took to get there, differs completely. Practically, this matters: the anti-dandruff shampoo's ingredient list, cross-checked against its monograph, is close to the complete safety picture — the monograph *is* the finding. The minoxidil product's approval rested on trial data specific to that formulation, which isn't summarized on the label the same way.

What you still don't know. Which pathway any *new*, unfamiliar OTC hair product took to reach the shelf. A Drug Facts panel confirms drug status; it doesn't disclose which of the two roads got it there.

Walkthrough 2 — A hair dye box, checking what it isn't approved for

The situation. A permanent hair color box lists p-Phenylenediamine among its ingredients and includes a small companion product marketed as an "eyebrow tint touch-up..

Run the questions.

Q1, and the coal-tar hair dye check. PPD appears at a meaningful position in the ingredient list. The required caution statement about a preliminary patch test is present on the packaging, exactly as the coal-tar hair dye exemption requires.

The restriction worth checking specifically. The same regulation that requires that patch-test warning also states plainly: not for dyeing eyelashes or eyebrows. The companion "eyebrow touch-up" product sits directly against that restriction, at least on its face.

What you now know. This is precisely the kind of mismatch Question 1's scope-of-approval lesson — first taught by Volume Two's flagship colorant — exists to catch. A colorant's approval for one use doesn't extend automatically to an adjacent one, even when packaging invites the connection.

What you still don't know. Whether the eyebrow component actually uses a different, eye-area-appropriate colorant not subject to this specific restriction, or whether this is a genuine compliance gap. The label raises the question; it doesn't settle it — the same limit Volume Two's walkthrough already established, showing up again in a completely different product.

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Volume Four

Hair Care

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