

Carton Panel And Listing Extract

the panel copy of a cosmetic carton set beside the product listing prepared for the Food and Drug Administration
| Marked-up specimen

<https://www.editfast.com/editing-services/cosmetics>

One product described twice, where the two descriptions disagree on a name, an address and an ingredient list.

ORIGINAL, WITH EDITS MARKED

SPECIMEN, PREPARED BY EDITFAST FOR ILLUSTRATION. NOT A REAL PACKAGE.

Prepared for Ellery Lane Beauty (fictitious), carton copy and listing extract

EXTRACT FROM THE COMPANY'S RECORD (reproduced unchanged in both panels)

CR-1 Product name as approved for the carton: Midnight Restore Night Balm.

CR-2 Name entered on the draft FDA product listing: Night Balm (Restore).

CR-3 Ingredients as supplied by formulation, in descending order: shea butter, caprylic triglyceride, squalane, tocopherol, fragrance.

CR-4 The fragrance is a compounded blend of eleven materials. The company holds the full list from its supplier.

CR-5 Adverse event contact monitored by the company: the postal address at Ellery Lane and the address care@ellerylane.example. The telephone line printed on the carton was discontinued in March.

CR-6 The company has not decided how the fragrance is to be entered on the listing.

CARTON BACK PANEL

Midnight Restore Night Balm

Ingredients: Shea Butter, Caprylic Triglyceride, Squalane, Tocopherol, Fragrance.

Questions? Call 1-800-555-0143.¹

DRAFT FDA PRODUCT LISTING (extract)

Product name: Night Balm (Restore)²

Ingredients: Shea Butter, Caprylic Triglyceride, Squalane, Tocopherol.³

WHAT CHANGED, AND WHY

#	Was	Now	Reason
1	Questions? Call 1-800-555-0143.	Questions or to report a problem with this product: Ellery Lane Beauty, Ellery Lane, or care@ellerylane.example.	Section 364e(a) requires a domestic address, domestic phone number, or electronic contact information through which the responsible person can receive adverse event reports, and 364a(d) provides that reports arrive through it. CR-5 records the telephone line as discontinued in March and names the two contacts the company monitors.
2	Product name: Night Balm (Restore)	Product name: Midnight Restore Night Balm	Section 364c(c)(4)(A)(ii) requires the listing to give "the name for the cosmetic product, as such name appears on the label." CR-1 gives the name approved for the carton, and CR-2 records a different string on the draft listing.
3	Ingredients: Shea Butter, Caprylic Triglyceride, Squalane, Tocopherol.	Ingredients: Shea Butter, Caprylic Triglyceride, Squalane, Tocopherol, Fragrance. / [Query to the company: CR-4 records the fragrance as a blend of eleven materials, and CR-6 records that no decision has been taken on how to enter it. Section 364c(c)(4)(A)(iv) names fragrances expressly and then points to 21 CFR 701.3 for how each ingredient is named, which is the section allowing fragrance to be listed as fragrance. The listing now carries the word the panel carries, and the question of whether the blend is itemized is left with the company.]	The listing extract omitted an ingredient the panel declares, and 364c(c)(4)(A)(iv) names fragrances among the things a listing includes. Whether the eleven materials are itemized is a question for the company, so the omission is closed and the question is raised rather than answered.