
Guidance for Industry Labeling OTC Skin Protectant Drug Products

DRAFT GUIDANCE

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**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)**

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OTC**

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**Guidance for Industry¹
Labeling OTC Skin Protectant Drug Products**

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This draft guidance is intended to describe the drug monograph for over-the-counter (OTC) skin protectant drug products, found in 21 CFR part 347. This guidance is intended to help interested parties understand the monograph for OTC skin protectant drug products and meet the requirements of the monograph. In the monograph, skin protectant drug products are defined as drug products that temporarily protect injured or exposed skin or mucous membrane surfaces from harmful or annoying stimuli and may help provide relief to such surfaces (§ 347.3). Skin protectant drug products include lip protectant drug products, typically referred to as *lip balms*. This guidance focuses on the labeling of skin protectant drug products with single or multiple skin protectant active ingredients as well as those containing skin protectant active ingredients combined with active ingredients from other OTC drug monographs. The guidance does not address issues or requirements related to skin protectant drug products used as astringents.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

We published numerous rulemakings related to OTC skin protectant drug products in the *Federal Register*. Below is a list of the significant skin protectant rulemakings addressed by this guidance:

¹ This guidance has been prepared by the Office of Nonprescription Products in the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration.

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- 43 • 1978 advance notice of proposed rulemaking (43 FR 34628): establishes a monograph for
44 OTC skin protectant drug products
- 45 • 1983 proposed rule (tentative final monograph) (48 FR 6820): proposed rule that
46 proposes generally recognized as safe and effective (GRASE) active ingredients and
47 required labeling for OTC skin protectant drug products
- 48 • 1989 proposed rule (54 FR 40808): proposes to amend the tentative final monograph to
49 include indications for the treatment of poison ivy, oak, and sumac and for the treatment
50 and/or neutralization of insect bites
- 51 • 2003 final rule (final monograph) (68 FR 33362): establishes GRASE active ingredients
52 and required labeling in 21 CFR part 347
- 53 • 2003 final rule (technical amendment) (68 FR 68509): provides additional labeling
54 claims that should not have been excluded from the final monograph
- 55 • 2008 final rule (technical amendment) (73 FR 6014): revises labeling requirements for lip
56 protectants
57

58 This guidance addresses the provisions of the 2003 final rule (68 FR 33362) as amended (68 FR
59 68509, 73 FR 6014), which are codified at 21 CFR part 347. The 2003 rule establishes the active
60 ingredients that may be used in OTC skin protectant drug products, how these active ingredients
61 may be combined with each other and with certain other classes of OTC active ingredients, and
62 the labeling requirements for OTC skin protectant drug products. The 2003 final rule
63 incorporates standardized labeling content and format requirements established by the FDA in
64 1999 (64 FR 13254, 21 CFR 201.66). In addition to other OTC skin protectant drug products,
65 the 2003 final rule addresses astringents. However, the 2003 final rule does not substantively
66 revise the requirements previously established in the 1993 final rule for OTC skin protectant
67 drug products used as astringents (58 FR 54458). Therefore, this guidance does not address
68 these drug products.²
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70

71 III. SKIN PROTECTANT ACTIVE INGREDIENTS

72 A. Which skin protectant active ingredients have special requirements?

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75 There are 19 GRASE OTC skin protectant active ingredients (§ 347.10). Three active
76 ingredients have special requirements: cod liver oil, colloidal oatmeal, and mineral oil. A skin
77 protectant drug product containing cod liver oil as an active ingredient also must include mineral
78 oil (§ 347.10(e)). In addition, a skin protectant drug product containing cod liver oil must be
79 labeled so that the quantity used in a 24-hour period does not exceed 10,000 USP units of
80 vitamin A and 400 USP units of vitamin D (cholecalciferol). A skin protectant drug product can
81 contain colloidal oatmeal at a minimum of 0.007 percent or mineral oil at a minimum of 50 to
82 100 percent as single active ingredients. However, a skin protectant drug product containing
83 both colloidal oatmeal and mineral oil must include a minimum of 0.003 percent colloidal
84 oatmeal and 30 to 35 percent mineral oil (§ 347.10).
85

² Astringent active ingredients that may be used in OTC drug products are listed in 21 CFR 347.12, and labeling requirements for these astringents are provided in 21 CFR 347.52.

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B. Which skin protectant active ingredients can be combined?

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88 Although there are some limitations, all skin protectant active ingredients except sodium
89 bicarbonate and topical starch can be combined with one or more of a subset of other skin
90 protectant active ingredients listed in § 347.10. A skin protectant drug product containing cod
91 liver oil also must contain another active ingredient (§ 347.10(e)). In all instances except the
92 combination of colloidal oatmeal and mineral oil, the allowed concentrations of each active
93 ingredient remain the same whether the active ingredient is used singly or in combination with
94 other active ingredients (§ 347.20). Section III.A. of this guidance describes the amounts of
95 colloidal oatmeal and mineral oil required when these ingredients are combined with each other.

96
97 The following lists identify the three groups of skin protectant active ingredients that can be
98 combined with each other according to § 347.20(a):

- 99
- 100 • Allantoin, cocoa butter, cod liver oil, dimethicone, glycerin, hard fat, lanolin,
101 mineral oil, petrolatum, white petrolatum
 - 102 • Aluminum hydroxide gel, calamine, kaolin, zinc acetate, zinc carbonate, zinc
103 oxide
 - 104 • Colloidal oatmeal, mineral oil

105
106 The active ingredients in each of these groups can be combined only with the other active
107 ingredients in the same group. Active ingredients in different groups cannot be used in the same
108 drug product. For example, cocoa butter can be combined with glycerin, but not with aluminum
109 hydroxide gel.

C. Can skin protectant active ingredients be combined with active ingredients from other OTC drug monographs?

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113
114 Yes, a skin protectant drug product from the first bulleted list above can contain external
115 analgesic, first aid antiseptic, or sunscreen active ingredients in combination with skin protectant
116 active ingredients (see §§ 347.20(b), (c), and (d)). Table I specifies which skin protectant active
117 ingredients can be combined with external analgesic, first aid antiseptic, or sunscreen active
118 ingredients.

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Table 1. Permitted Combinations of Skin Protectant Active Ingredients with Active Ingredients from Other OTC Drug Monographs

Skin Protectant Active Ingredients¹	Other Active Ingredients
Any one (or two if required to be in combination) of the following: allantoin, cocoa butter, cod liver oil, hard fat, lanolin, mineral oil, petrolatum, white petrolatum	With specified external analgesic or first aid antiseptic active ingredients
Any one (or two if required to be in combination) or more of the following: allantoin, cocoa butter, cod liver oil, dimethicone, glycerin, hard fat, lanolin, mineral oil, petrolatum, white petrolatum	With specified sunscreen active ingredients

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¹ For ease of reference, this list includes only active ingredient names. Permitted concentrations for skin protectant active ingredients are provided in 21 CFR 347.10. This table also does not address related labeling requirements.

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The specific active ingredients that may be combined could be expanded, reduced, or otherwise revised as we complete the rulemakings for OTC external analgesic, first aid antiseptic, and sunscreen drug products. As we complete these three final rules, we will revise the lists of permitted combinations in the skin protectant monograph (§§ 347.20(b), (c), and/or (d)) as needed to ensure consistency among all of these OTC drug monographs. We have issued tentative final monographs for OTC external analgesic and first aid antiseptic drug products (48 FR 5852 and 56 FR 33644, respectively). The tentative final monograph for external analgesic drug products would allow combinations of specified external analgesic active ingredients singly or in combination with specified, single, or combination skin protectant ingredients (proposed 348.20(b)). The tentative final monograph for first aid antiseptic active ingredients allows combinations only of specified, single first aid antiseptic ingredients with single skin protectant ingredients (proposed 333.20(b)).

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Until we issue final rules for external analgesic and first aid antiseptic drug products, we do not intend to take enforcement action if an OTC drug product combines external analgesic or first aid antiseptic active ingredients identified in these tentative final monographs with applicable skin protectant active ingredients listed in Table 1 if the drug product is labeled with skin protectant claims (§ 347.60(b)(1) or (2)) and either external analgesic claims (proposed 348.20(b)(1)) or first aid antiseptic claims (proposed 330.60) as appropriate (CPG 450.300).

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We stayed the effective date of the final monograph for OTC sunscreen drug products (21 CFR part 352) so that we could address ultraviolet A testing and labeling (66 FR 67485). In 2007, we proposed revisions to this monograph, including a revision to add two more permissible combinations of sunscreen active ingredients with skin protectant active ingredients (72 FR 49070). Until a final monograph for OTC sunscreen drug products becomes effective, we do not intend to take enforcement action if an OTC drug product contains combinations of any sunscreen active ingredients identified in § 352.10 (including those proposed in 2007) with the applicable skin protectant active ingredients listed in Table 1 if the drug product is labeled with claims in § 347.60(b)(3) and § 352.60(b).

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157 **D. Are there any ingredients that cannot be used as skin protectant active**
158 **ingredients?**
159

160 Yes. The only ingredients that can be used as skin protectant active ingredients are those listed
161 in § 347.10. Other active ingredients that have been used in OTC skin protectant drug products
162 are listed in 21 CFR 310.545(a)(18). We have not received sufficient data to establish that the
163 ingredients in 21 CFR 310.545(a)(18) are GRASE. Therefore, these ingredients are not
164 permitted as skin protectant active ingredients under the monograph.
165

166
167 **IV. LABELING FOR OTC SKIN PROTECTANT DRUG PRODUCTS**
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169 **A. What are the general labeling content and format requirements?**
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171 General labeling requirements for drug products are provided in 21 CFR part 201 and part 330,
172 subpart A. After the tentative final monograph for OTC skin protectant drug products was
173 published in 1983, we issued a 1999 final rule standardizing the content and format for labeling
174 OTC drug products (64 FR 13254). Among other changes, the final rule revised 21 CFR part
175 201 to include § 201.66, which requires that OTC drug products include a Drug Facts box
176 containing each active ingredient and corresponding purpose (statement of identity), indications,
177 warnings, directions, and other information.
178

179 The attachment to this guidance provides a sample Drug Facts box for an OTC skin protectant
180 drug product that would comply with the requirements of § 201.66 and the other regulations
181 described in this guidance. Additional guidance on labeling of OTC drug products can be found
182 on our Web site (<http://www.fda.gov/cder/guidance/index.htm>).
183

184 **B. What is the appropriate statement of identity (*Purpose*) for my drug**
185 **product?**
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187 The statement of identity must appear on the principal display panel according to § 201.61 and
188 must include the established name, if any, and the general pharmacological category(ies) or the
189 principal intended action(s). The established name also must appear in the Drug Facts box under
190 the *Active ingredient* heading. The general pharmacological category(ies) or the principal
191 intended action(s) also must appear in the Drug Facts box under the *Purpose* heading, in
192 accordance with §§ 201.66(c)(2) and (3), respectively.
193

194 In addition, every OTC skin protectant drug product must include one or more of the following
195 specified descriptors in the statement of identity:
196

- 197 • Any OTC skin protectant drug product may include “skin protectant” in the statement of
198 identity (§ 347.50(a)(1)).
- 199 • An OTC skin protectant formulated as a lip protectant may include “lip protectant” or
200 “lip balm” (§ 347.50(a)(2)).