
Guidance for Industry Labeling OTC Skin Protectant Drug Products

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact Michael Koenig at 301-796-2090.

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

**August 2008
OTC**

Guidance for Industry Labeling OTC Skin Protectant Drug Products

Additional copies are available from:

*Office of Training and Communications
Division of Drug Information
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, rm. 2201
Silver Spring, MD 20993-0002
E-mail: druginfo@fda.hhs.gov
Fax: 301-847-8714
(Tel) 301-796-3400
<http://www.fda.gov/cder/guidance/index.htm>*

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

**August 2008
OTC**

TABLE OF CONTENTS

I. INTRODUCTION..... 1

II. BACKGROUND 1

III. SKIN PROTECTANT ACTIVE INGREDIENTS 2

A. Which skin protectant active ingredients have special requirements? 2

B. Which skin protectant active ingredients can be combined?..... 3

C. Can skin protectant active ingredients be combined with active ingredients from other OTC drug monographs? 3

D. Are there any ingredients that cannot be used as skin protectant active ingredients? 5

IV. LABELING FOR OTC SKIN PROTECTANT DRUG PRODUCTS..... 5

A. What are the general labeling content and format requirements? 5

B. What is the appropriate statement of identity (*Purpose*) for my drug product? 5

C. What are the appropriate indications (*Uses*) for my drug product?..... 6

D. What are the appropriate *Warnings* for my drug products? 7

E. What are the appropriate *Directions* for my drug product?..... 9

V. SPECIAL LABELING REQUIREMENTS OR EXCEPTIONS FOR SKIN PROTECTANT DRUG PRODUCTS 10

A. Are lip protectants with small packaging allowed reduced labeling? 10

B. Are skin protectant drug products containing cocoa butter, petrolatum, and/or white petrolatum allowed reduced labeling? 11

C. What are the labeling requirements for skin protectant drug products containing active ingredients from other OTC drug monographs?..... 12

ATTACHMENT: HAND LOTION CONTAINING 25% DIMETHICONE 13

Contains Nonbinding Recommendations

Draft — Not for Implementation

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.

Contains Nonbinding Recommendations

Draft — Not for Implementation

- 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

III. SKIN PROTECTANT ACTIVE INGREDIENTS

A. Which skin protectant active ingredients have special requirements?

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).

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.

Contains Nonbinding Recommendations

Draft — Not for Implementation

B. Which skin protectant active ingredients can be combined?

86
87
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?

110
111
112
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 1 specifies which skin protectant active
117 ingredients can be combined with external analgesic, first aid antiseptic, or sunscreen active
118 ingredients.
119

Contains Nonbinding Recommendations

Draft — Not for Implementation

120 **Table 1. Permitted Combinations of Skin Protectant Active Ingredients with Active**
121 **Ingredients from Other OTC Drug Monographs**
122

Skin Protectant Active Ingredients ¹	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

123 ¹ For ease of reference, this list includes only active ingredient names. Permitted concentrations for skin
124 protectant active ingredients are provided in 21 CFR 347.10. This table also does not address related
125 labeling requirements.
126

127 The specific active ingredients that may be combined could be expanded, reduced, or otherwise
128 revised as we complete the rulemakings for OTC external analgesic, first aid antiseptic, and
129 sunscreen drug products. As we complete these three final rules, we will revise the lists of
130 permitted combinations in the skin protectant monograph (§§ 347.20(b), (c), and/or (d)) as
131 needed to ensure consistency among all of these OTC drug monographs. We have issued
132 tentative final monographs for OTC external analgesic and first aid antiseptic drug products (48
133 FR 5852 and 56 FR 33644, respectively). The tentative final monograph for external analgesic
134 drug products would allow combinations of specified external analgesic active ingredients singly
135 or in combination with specified, single, or combination skin protectant ingredients (proposed
136 348.20(b)). The tentative final monograph for first aid antiseptic active ingredients allows
137 combinations only of specified, single first aid antiseptic ingredients with single skin protectant
138 ingredients (proposed 333.20(b)).
139

140 Until we issue final rules for external analgesic and first aid antiseptic drug products, we do not
141 intend to take enforcement action if an OTC drug product combines external analgesic or first
142 aid antiseptic active ingredients identified in these tentative final monographs with applicable
143 skin protectant active ingredients listed in Table 1 if the drug product is labeled with skin
144 protectant claims (§ 347.60(b)(1) or (2)) and either external analgesic claims (proposed
145 348.20(b)(1)) or first aid antiseptic claims (proposed 330.60) as appropriate (CPG 450.300).
146

147 We stayed the effective date of the final monograph for OTC sunscreen drug products (21 CFR
148 part 352) so that we could address ultraviolet A testing and labeling (66 FR 67485). In 2007, we
149 proposed revisions to this monograph, including a revision to add two more permissible
150 combinations of sunscreen active ingredients with skin protectant active ingredients (72 FR
151 49070). Until a final monograph for OTC sunscreen drug products becomes effective, we do not
152 intend to take enforcement action if an OTC drug product contains combinations of any
153 sunscreen active ingredients identified in § 352.10 (including those proposed in 2007) with the
154 applicable skin protectant active ingredients listed in Table 1 if the drug product is labeled with
155 claims in § 347.60(b)(3) and § 352.60(b).
156

Contains Nonbinding Recommendations

Draft — Not for Implementation

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**
168

169 **A. What are the general labeling content and format requirements?**
170

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?**
186

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)).

Contains Nonbinding Recommendations

Draft — Not for Implementation

- 201 • Those OTC skin protectant drug products containing the following six active ingredients
202 may include “poison ivy, oak, sumac drying”: aluminum hydroxide gel, calamine, kaolin,
203 zinc acetate, zinc carbonate, and zinc oxide (§ 347.50(a)(3)).
204 • OTC skin protectant drug products containing any of the above six active ingredients, or
205 colloidal oatmeal or sodium bicarbonate, may include “poison ivy, oak, sumac
206 protectant” (§ 347.50(a)(4)).
207

208 The statement of identity for any OTC skin protectant drug product also may include the dosage
209 form. For example, the statement of identity for a lotion containing cocoa butter could be either
210 “skin protectant” or “skin protectant lotion” (§ 347.50(a)(1)).
211

212 C. What are the appropriate indications (*Uses*) for my drug product?

213
214 The indication(s) must appear in the Drug Facts box under the *Uses* heading in accordance with
215 §§ 201.66(c)(4) and 347.50(b). Table 2 provides skin protectant indication statements that can
216 be made under the *Uses* heading, including optional language for certain active ingredients.³
217 Skin protectant indication statements are included in the labeling whenever a skin protectant
218 active ingredient is present in a drug product, whether as a single active ingredient or in
219 combination with other skin protectant, external analgesic, first aid antiseptic, or sunscreen
220 active ingredients (see sections III.B. and C.).
221

222 **Table 2. Skin Protectant Indications**

Skin Protectant Active Ingredients ¹	Indications (<i>Uses</i>) ²
allantoin, cocoa butter, cod liver oil, hard fat, lanolin, mineral oil, petrolatum, white petrolatum	<ul style="list-style-type: none">temporarily protects minor cutsscrapesburns
allantoin, cocoa butter, cod liver oil, dimethicone, glycerin, hard fat, lanolin, mineral oil, petrolatum, white petrolatum	<p><u>If not formulated and labeled as a lip protectant:</u></p> <ul style="list-style-type: none"><i>helps prevent and temporarily protects and helps relieve chafed, chapped or cracked skin and lips</i>
	<p><u>If formulated and labeled as a lip protectant:</u></p> <ul style="list-style-type: none">temporarily protects <i>and helps relieve chafed, chapped or cracked lips</i>
	<p><u>Optional for both:</u></p> <ul style="list-style-type: none"><i>helps prevent and protect from the drying effects of wind and cold weather</i>³

³ Other truthful and nonmisleading statements, describing only the uses that have been established and listed in 21 CFR 347.50(b), also may be used as provided in 21 CFR 330.1(c)(2).

Contains Nonbinding Recommendations

Draft — Not for Implementation

Skin Protectant Active Ingredients ¹	Indications (Uses) ²
cocoa butter, petrolatum, white petrolatum <i>not</i> marketed as a lip protectant	Select one of the following: ³ <ul style="list-style-type: none">• Use helps protect minor cuts and burns• Use helps <i>prevent and</i> protect chapped skin• Use helps protect minor cuts and burns and <i>prevent and protect</i> chapped skin
aluminum hydroxide gel, calamine, kaolin, zinc acetate, zinc carbonate, zinc oxide	<ul style="list-style-type: none">• dries the oozing and weeping of poison: • ivy<ul style="list-style-type: none">• oak• sumac
colloidal oatmeal	<ul style="list-style-type: none">• temporarily protects and helps relieve minor skin irritation and itching due to: [select one or more of the following:]⁴ • rashes • eczema • poison ivy, oak, or sumac • insect bites
sodium bicarbonate	<ul style="list-style-type: none">• temporarily protects and helps relieve minor skin irritation and itching due to:<ul style="list-style-type: none">• poison ivy, oak, or sumac• insect bites
topical starch	<ul style="list-style-type: none">• temporarily protects and helps relieve minor skin irritation
colloidal oatmeal combined with mineral oil	<ul style="list-style-type: none">• temporarily protects and helps relieve minor skin irritation and itching due to: [select one of the following:]⁴ • rashes • eczema

224 ¹ For ease of reference, this list includes only active ingredient names. Permitted concentrations for skin
225 protectant active ingredients are provided in 21 CFR 347.10.

226 ² Bolded, underlined language and bolded language in brackets is explanatory; not to be included in
227 labeling. Italicized language is optional.

228 ³ This entire bulleted statement is optional. If this statement is not included in labeling, do not place a
229 bullet before the remaining statement.

230 ⁴ If only one term is used, do not use a bullet.

231

232 **D. What are the appropriate *Warnings* for my drug products?**

233

234 There are a few warnings that are required in the labeling of OTC skin protectant drug products
235 (§§ 201.66(c)(5) and 347.50(c)). The skin protectant active ingredient and, in some cases, the
236 labeled indication (as shown in Table 3) determine which warnings are required.

237

Contains Nonbinding Recommendations

Draft — Not for Implementation

Table 3. Skin Protectant Warnings

238
239

Active Ingredients and Indications¹	Warnings
all active ingredients <i>except</i> <ul style="list-style-type: none"> • cocoa butter, petrolatum, or white petrolatum,² • those formulated and labeled as lip protectants that meet the criteria in § 201.66(d)(10) 	When using this product <ul style="list-style-type: none"> • do not get into eyes Stop use and ask a doctor if <ul style="list-style-type: none"> • condition worsens • symptoms last more than 7 days or clear up and occur again within a few days
cocoa butter, petrolatum, or white petrolatum <i>not</i> marketed as a lip protectant	<ul style="list-style-type: none"> • Do not get into eyes • See a doctor if condition lasts more than 7 days • Do not use on <ul style="list-style-type: none"> • deep or puncture wounds • animal bites • serious burns
allantoin, cod liver oil, dimethicone, glycerin, hard fat, lanolin, mineral oil <i>except</i> if they are formulated and labeled as a lip protectant that meets the criteria in § 201.66(d)(10)	Do not use on <ul style="list-style-type: none"> • deep or puncture wounds • animal bites • serious burns
all active ingredients <i>not</i> formulated and labeled as a lip protectant that meets the criteria in § 201.66(d)(10)	Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
all active ingredients <i>except</i> <ul style="list-style-type: none"> • mineral oil or sodium bicarbonate if labeling for oral use is included • cocoa butter, petrolatum, or white petrolatum² • if drug product is formulated and labeled as a lip protectant that meets the criteria in § 201.66(d)(10) 	For external use only
kaolin or topical starch in powder products	Do not use <ul style="list-style-type: none"> • on broken skin When using this product <ul style="list-style-type: none"> • keep away from face and mouth to avoid breathing it
colloidal oatmeal labeled for use as a soak in a tub	When using this product <ul style="list-style-type: none"> • to avoid slipping, use mat in tub or shower
colloidal oatmeal or sodium bicarbonate labeled for use as soak, compress, or wet dressing	When using this product <ul style="list-style-type: none"> • in some skin conditions, soaking too long may overdry

240
241
242
243
244

¹ For ease of reference, this list includes only names of active ingredients. Permitted concentrations for skin protectant active ingredients are listed in § 347.10.

² Use these warnings if drug product contains other active ingredients in addition to cocoa butter, petrolatum, or white petrolatum.

Contains Nonbinding Recommendations

Draft — Not for Implementation

245 **E. What are the appropriate *Directions* for my drug product?**

246
247 The directions for an OTC skin protectant drug product are determined by the active ingredient
248 and by dosage form for colloidal oatmeal and sodium bicarbonate, as described in Table 4.

249
250 If specific directions are not listed in Table 4 for a particular active ingredient, the directions are
251 “apply as needed,” in accordance with § 347.50(d).

252
253 **Table 4. Skin Protectant Directions**

Active Ingredients and Dosage Form ¹	Directions ²
colloidal oatmeal	<p><u>For products requiring dispersal in water:</u></p> <ul style="list-style-type: none">• turn warm water faucet on to full force• slowly sprinkle (insert amount) of colloidal oatmeal directly under the faucet into the tub or container³• stir any colloidal oatmeal settled on the bottom <p><u>For products to be used as a soak in a bath:</u>⁴</p> <p>For use as a soak in a bath:</p> <ul style="list-style-type: none">• soak affected area for 15 to 30 minutes as needed, or as directed by a doctor• pat dry (do not rub) to keep a thin layer on the skin <p><u>For products to be used as a compress or wet dressing:</u>⁴</p> <p>For use as a compress or wet dressing:</p> <ul style="list-style-type: none">• soak a clean, soft cloth in the mixture• apply cloth loosely to affected area for 15 to 30 minutes• repeat as needed or as directed by a doctor• discard mixture after each use
sodium bicarbonate	<ul style="list-style-type: none">• adults and children 2 years of age and over: <p><u>For products to be used as a soak in a bath:</u></p> <p>For use as a soak in a bath:</p> <ul style="list-style-type: none">• dissolve 1 to 2 cupfuls in a tub of warm water• soak for 10 to 30 minutes as needed, or as directed by a doctor• pat dry (do not rub) to keep a thin layer on the skin• children under 2 years: ask a doctor

Contains Nonbinding Recommendations

Draft — Not for Implementation

Active Ingredients and Dosage Form ¹	Directions ²
sodium bicarbonate (continued)	<p data-bbox="790 270 1349 333"><u>For products to be used as a compress or wet dressing:</u></p> <p data-bbox="790 371 1240 401">For use as a compress or wet dressing:</p> <ul data-bbox="813 407 1386 680" style="list-style-type: none">• add sodium bicarbonate to water to make a mixture in a container• soak a clean, soft cloth in the mixture• apply cloth loosely to affected area for 15 to 30 minutes• repeat as needed or as directed by a doctor• discard mixture after each use• children under 2 years: ask a doctor <p data-bbox="790 720 1224 749"><u>For products to be used as a paste:</u></p> <p data-bbox="790 787 1003 816">For use as a paste:</p> <ul data-bbox="813 823 1386 989" style="list-style-type: none">• add enough water to the sodium bicarbonate to form a paste• apply to the affected area of the skin as needed, or as directed by a doctor• children under 2 years: ask a doctor
aluminum hydroxide gel	<ul data-bbox="790 1039 1252 1068" style="list-style-type: none">• children under 6 months: ask a doctor
glycerin	<ul data-bbox="790 1115 1252 1144" style="list-style-type: none">• children under 6 months: ask a doctor
zinc acetate	<ul data-bbox="790 1176 1230 1205" style="list-style-type: none">• children under 2 years: ask a doctor

255 ¹ For ease of reference, this list includes only active ingredient names. Permitted concentrations for skin
256 protectant active ingredients are provided in 21 CFR 347.10.

257 ² Bolded, underlined language is explanatory and not to be included in labeling.

258 ³ Parentheses mark insertion point for colloidal oatmeal amount and should not be included in labeling.

259 ⁴ Manufacturer also must include adequate directions to obtain solution with appropriate concentration of
260 colloidal oatmeal in accordance with 21 CFR 347.50(d)(2)(A) and (B).

261

262

263

V. SPECIAL LABELING REQUIREMENTS OR EXCEPTIONS FOR SKIN PROTECTANT DRUG PRODUCTS

264

265

266

A. Are lip protectants with small packaging allowed reduced labeling?

267

268

269 Yes, OTC lip protectant drug products are allowed reduced labeling if marketed in small
270 packages with space limitations specified in 21 CFR 201.66(d)(10). Much of this abbreviated
271 labeling is captured in Tables 2 through 4, but the following list summarizes all otherwise
272 required labeling that can be omitted for these lip protectants (§ 347.50(e)):

Contains Nonbinding Recommendations

Draft — Not for Implementation

- 273 • *Drug Facts* title
- 274 • *Purpose* heading and related information
- 275 • All information under *Warnings*
- 276 • *Directions* heading and related information
- 277 • *Other information* heading
- 278 • Horizontal barlines and hairlines described in § 201.66(d)(8)

279
280 In addition, the *Uses* heading and indication statement may be reduced to the following: “**Use**
281 helps *prevent*, protect, and *relieve* chapped lips” (italicized language is optional). The active
282 ingredients should be listed in alphabetical order.

283
284 **B. Are skin protectant drug products containing cocoa butter, petrolatum,**
285 **and/or white petrolatum allowed reduced labeling?**
286

287 Yes, OTC skin protectant drug products containing cocoa butter, petrolatum, or white petrolatum
288 as a single active ingredient or in combination with each other are allowed reduced labeling as
289 specified in 21 CFR 347.50(f). Much of this reduced labeling is captured in Tables 2 through 4,
290 but the following lists summarize all otherwise required labeling that can be omitted or reduced
291 for these drug products (§ 347.50(f)):

292
293 The following labeling may be omitted:

- 294
- 295 • *Purpose* heading and related information
- 296 • **For external use only**
- 297 • *Other information* heading and related information

298
299 *Uses* heading and indication statement may be reduced to one of the following statements
300 (italicized language is optional):

- 301
- 302 • “**Use** helps protect minor cuts and burns”
- 303 • “**Use** helps *prevent and* protect chapped skin”
- 304 • “**Use** helps protect minor cuts and burns and *prevent and protect* chapped skin”

305
306 As stated in § 347.50(f)(1)(iii) and (iv), *Warnings* must contain the following shortened
307 statements or the corresponding full-length statements listed in § 347.50(c):

- 308
- 309 • “*See a doctor if condition lasts more than 7 days*”
- 310 • “**When using this product** do not get into eyes”
- 311 • “**Do not use on** • deep or puncture wound • animal bites • serious burns”

312
313 The active ingredients should be listed in alphabetical order.

314

Contains Nonbinding Recommendations

Draft — Not for Implementation

315 **C. What are the labeling requirements for skin protectant drug products**
316 **containing active ingredients from other OTC drug monographs?**
317

318 Table 1 lists the skin protectant active ingredients that may be combined with active ingredients
319 from other OTC drug monographs, specifically external analgesic, first aid antiseptic, and
320 sunscreen active ingredients. If skin protectant active ingredients are combined with active
321 ingredients from these specified OTC drug monographs, the labeling requirements of each
322 applicable OTC drug monograph must be met.
323

324 However, as set forth in § 347.60, labeling statements can be combined to eliminate duplicative
325 words and phrases to produce clear, understandable statements that include all required
326 information.⁴ In some cases, there may be conflicting dosing directions such as different time
327 intervals between doses or different minimum age limits. In such situations, the directions must
328 not include a dosage that exceeds the dosage established for any individual active ingredient, and
329 the minimum age limit must be the highest established for any individual active ingredient. For
330 example, if one active ingredient can be used by children 12 years of age and over while another
331 active ingredient can be used by children 6 years of age and over, then the drug product should
332 be labeled for use by children 12 years of age and over.
333

334 Cosmetic ingredients and skin protectant active ingredients may be combined in a single product
335 as long as cosmetic ingredients and drug active ingredients are listed separately. All of the
336 cosmetic ingredients appear under the *Inactive ingredients* heading in the Drug Facts box, in the
337 manner set forth in 21 CFR 201.66(c)(8) and 701.3(d). However, any cosmetic claims should
338 appear outside the Drug Facts box.
339

⁴ When we issued the final rule for OTC skin protectant drug products in 2003, we lifted the stay on the sunscreen final rule (21 CFR part 352) and amended the sunscreen rule to include sunscreen-skin protectant combination drug products. In the same 2003 final rule, we then reinstated the stay on part 352 and also stayed § 347.20(d), the provision of the skin protectant monograph addressing combination sunscreen-skin protectant drug products. As discussed above, we published a proposed rule in 2007 to revise the sunscreen monograph. In the 2007 proposed rule, we propose that the stays of both part 352 and § 347.20(d) be lifted when that proposed rule is finalized. Accordingly, we currently intend to maintain these stays until a final rule based on the 2007 sunscreen proposed rule becomes effective. In the interim, sunscreen manufacturers are encouraged, but not required, to adhere to the regulations set forth in part 352 and § 347.20(d), as revised in the 2007 sunscreen proposed rule, regarding combinations of skin protectant and sunscreen active ingredients.

Contains Nonbinding Recommendations

Draft — Not for Implementation

340
341
342
343

ATTACHMENT: HAND LOTION CONTAINING 25% DIMETHICONE

Drug Facts	
Active ingredients	Purpose
Dimethicone, 25%.....	Skin Protectant
Uses	
<ul style="list-style-type: none">temporarily protects and helps relieve chapped or cracked skinhelps protect from the drying effects of wind and cold weather	
Warnings	
For external use only	
Do not use on	
<ul style="list-style-type: none">deep or puncture woundsanimal bitesserious burns	
When using this product	
<ul style="list-style-type: none">do not get into eyes	
Stop use and ask a doctor if	
<ul style="list-style-type: none">condition worsenssymptoms last more than 7 days or clear up and occur again within a few days	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions	
<ul style="list-style-type: none">apply as needed	
Other information	
<ul style="list-style-type: none">store at 20-25°C (68-77°F)	
Inactive ingredients [list of inactive ingredients in alphabetical order]	
Questions or comments? call toll free 1-800-xxx-xxxx	

344
345
346
347
348

Note: Font, font size, and font attributes (e.g., bold) shown above comply with Drug Facts format specifications in 21 CFR 201.66(d).