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DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.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be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance.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

Guidance for Industry[1]
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This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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This draft guidance is intended to describe the drug monograph for over-the-counter (OTC) skin protectant drug products, found in 21 CFR part 347.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.

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

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

III. SKIN PROTECTANT ACTIVE INGREDIENTS

A. Which skin protectant active ingredients have special requirements?

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

B. Which skin protectant active ingredients can be combined?

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

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

- Allantoin, cocoa butter, cod liver oil, dimethicone, glycerin, hard fat, lanolin, mineral oil, petrolatum, white petrolatum
- Aluminum hydroxide gel, calamine, kaolin, zinc acetate, zinc carbonate, zinc oxide
- Colloidal oatmeal, mineral oil

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

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

Yes, a skin protectant drug product from the first bulleted list above can contain external analgesic, first aid antiseptic, or sunscreen active ingredients in combination with skin protectant active ingredients (see §§ 347.20(b), (c), and (d)). Table 1 specifies which skin protectant active ingredients can be combined with external analgesic, first aid antiseptic, or sunscreen active ingredients.

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

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

[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.

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)).

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).

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).

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

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

IV. LABELING FOR OTC SKIN PROTECTANT DRUG PRODUCTS

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

General labeling requirements for drug products are provided in 21 CFR part 201 and part 330, subpart A. After the tentative final monograph for OTC skin protectant drug products was published in 1983, we issued a 1999 final rule standardizing the content and format for labeling OTC drug products (64 FR 13254). Among other changes, the final rule revised 21 CFR part 201 to include § 201.66, which requires that OTC drug products include a Drug Facts box containing each active ingredient and corresponding purpose (statement of identity), indications, warnings, directions, and other information.

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

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

The statement of identity must appear on the principal display panel according to § 201.61 and must include the established name, if any, and the general pharmacological category(ies) or the principal intended action(s). The established name also must appear in the Drug Facts box under the *Active ingredient* heading. The general pharmacological category(ies) or the principal intended action(s) also must appear in the Drug Facts box under the *Purpose* heading, in accordance with §§ 201.66(c)(2) and (3), respectively.

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

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

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

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

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

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

Table 2. Skin Protectant Indications

Skin Protectant Active Ingredients[1]	Indications (Uses)[2]
allantoin, cocoa butter, cod liver oil, hard fat, lanolin, mineral oil, petrolatum, white petrolatum	• temporarily protects minor • cuts • scrapes • burns
allantoin, cocoa butter, cod liver oil, dimethicone, glycerin, hard fat, lanolin, mineral oil, petrolatum, white petrolatum	**<u>If not formulated and labeled as a lip protectant:</u>** • *helps prevent and* temporarily protects *and helps relieve chafed*, chapped or cracked skin *and lips* **<u>If formulated and labeled as a lip protectant</u>**: • temporarily protects *and helps relieve chafed*, chapped or cracked lips **<u>Optional for both:</u>** • *helps prevent and protect from the drying effects of wind and cold weather*[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).

Skin Protectant Active Ingredients[1]	Indications (Uses)[2]
cocoa butter, petrolatum, white petrolatum *not* marketed as a lip protectant	**Select one of the following**:[3] • **Use** helps protect minor cuts and burns • **Use** helps *prevent and* protect chapped skin • **Use** helps protect minor cuts and burns and *prevent and protect* chapped skin
aluminum hydroxide gel, calamine, kaolin, zinc acetate, zinc carbonate, zinc oxide	• dries the oozing and weeping of poison: • ivy • oak • sumac
colloidal oatmeal	• 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	• temporarily protects and helps relieve minor skin irritation and itching due to: • poison ivy, oak, or sumac • insect bites
topical starch	• temporarily protects and helps relieve minor skin irritation
colloidal oatmeal combined with mineral oil	• temporarily protects and helps relieve minor skin irritation and itching due to: **[select one of the following:]**[4] • rashes • eczema

[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.

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

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

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

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

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

238 **Table 3. Skin Protectant Warnings**
239

Active Ingredients and Indications[1]	Warnings
all active ingredients *except* • 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** • do not get into eyes **Stop use and ask a doctor if** • condition worsens • symptoms last more than 7 days or clear up and occur again within a few days
cocoa butter, petrolatum, or white petrolatum *not* marketed as a lip protectant	• Do not get into eyes • See a doctor if condition lasts more than 7 days • **Do not use** on • deep or puncture wounds • animal bites • serious burns
allantoin, cod liver oil, dimethicone, glycerin, hard fat, lanolin, mineral oil *except* if they are formulated and labeled as a lip protectant that meets the criteria in § 201.66(d)(10)	**Do not use** on • deep or puncture wounds • animal bites • serious burns
all active ingredients *not* 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 *except* • mineral oil or sodium bicarbonate if labeling for oral use is included • cocoa butter, petrolatum, or white petrolatum[2] • 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** • on broken skin **When using this product** • 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** • 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** • in some skin conditions, soaking too long may overdry

240 [1] For ease of reference, this list includes only names of active ingredients. Permitted concentrations for
241 skin protectant active ingredients are listed in § 347.10.
242 [2] Use these warnings if drug product contains other active ingredients in addition to cocoa butter,
243 petrolatum, or white petrolatum.
244

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

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

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

Table 4. Skin Protectant Directions

Active Ingredients and Dosage Form[1]	Directions[2]
colloidal oatmeal	**<u>For products requiring dispersal in water</u>**: • turn warm water faucet on to full force • slowly sprinkle (insert amount) of colloidal oatmeal directly under the faucet into the tub or container[3] • stir any colloidal oatmeal settled on the bottom **<u>For products to be used as a soak in a bath</u>:**[4] For use as a soak in a bath: • 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 **<u>For products to be used as a compress or wet dressing</u>:**[4] For use as a compress or wet dressing: • 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	• adults and children 2 years of age and over: **<u>For products to be used as a soak in a bath</u>:** For use as a soak in a bath: • 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

Active Ingredients and Dosage Form[1]	Directions[2]
sodium bicarbonate (continued)	**For products to be used as a compress or wet dressing:** For use as a compress or wet dressing: • 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 **For products to be used as a paste:** For use as a paste: • 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	• children under 6 months: ask a doctor
glycerin	• children under 6 months: ask a doctor
zinc acetate	• children under 2 years: ask a doctor

[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.
[2] Bolded, underlined language is explanatory and not to be included in labeling.
[3] Parentheses mark insertion point for colloidal oatmeal amount and should not be included in labeling.
[4] Manufacturer also must include adequate directions to obtain solution with appropriate concentration of colloidal oatmeal in accordance with 21 CFR 347.50(d)(2)(A) and (B).

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

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

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

- *Drug Facts* title
- *Purpose* heading and related information
- All information under *Warnings*
- *Directions* heading and related information
- *Other information* heading
- Horizontal barlines and hairlines described in § 201.66(d)(8)

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

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

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

The following labeling may be omitted:

- *Purpose* heading and related information
- **For external use only**
- *Other information* heading and related information

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

- "**Use** helps protect minor cuts and burns"
- "**Use** helps *prevent and* protect chapped skin"
- "**Use** helps protect minor cuts and burns and *prevent and protect* chapped skin"

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

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

The active ingredients should be listed in alphabetical order.

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

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

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

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

[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 suncreen 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.

ATTACHMENT: HAND LOTION CONTAINING 25% DIMETHICONE

Drug Facts

Active ingredients ***Purpose***
Dimethicone, 25%.....Skin Protectant

Uses
- temporarily protects and helps relieve chapped or cracked skin
- helps protect from the drying effects of wind and cold weather

Warnings
For external use only

Do not use on
- deep or puncture wounds
- animal bites
- serious burns

When using this product
- do not get into eyes

Stop use and ask a doctor if
- condition worsens
- symptoms 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
- apply as needed

Other information
- 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**

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