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September 11, 2000

Ms. Jennie Butler
Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

**RE: Withdrawal of Previously Submitted Applications for Exemptions
Resubmission of Application for Exemption
Docket No. 98N-0337
Skin Protectant Lip Balms**

Dear Sir/Madam:

Reference is made to the FDA Federal Register publication of March 17, 1999 (64 FR 13254); Over-The-Counter Human Drugs; Labeling Requirements. This final rule establishes a standardized format for labeling of over-the-counter (OTC) drug products to provide consumers with OTC drug product labeling that is easy to read and understand. Further reference is made to the letter, dated August 9, 1999, from Charles J. Ganley, M.D. (Division of OTC Drug Products) to R. William Soller, Ph.D. (Consumer HealthCare Products Association). This letter outlines the procedures for submitting exemptions and deferrals from the requirements set forth in the labeling requirements for OTC drugs, 21 CFR 201.66 (e).

Pursuant to requirements established in these documents, on March 10, 2000, Whitehall-Robins petitioned FDA to allow certain exemptions from labeling requirements for Chap Stick lip balm products with active ingredients consisting of only skin protectants, skin protectants with sunscreen, or skin protectants with external analgesics. Whitehall-Robins hereby withdraws the three cited petitions as discussed with the Agency on September 8, 2000.

In accordance with 21 CFR 201.66 (e), Whitehall-Robins hereby requests a product or category-specific small package exemption from some provisions of 21 CFR 201.66 (OTC Labeling Format) for the skin protectant Chap Stick line of lip balm products. The final rule for labeling OTC Drug Products, 64 FR 13254 at 13270, states "In some cases (e.g., lipsticks or lip balms containing sunscreen), minimal information is needed for the safe and effective use of the product." The Chap Stick products have these characteristics which make them candidates for an appropriate exemption.

98N-0337

APP10

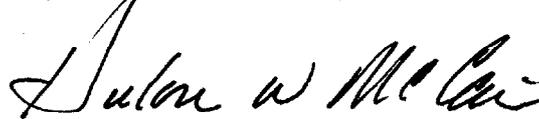
0409
SEP 14 2000

Enclosed are samples of current stick labeling and labeling that illustrates the amount of overflow text when the labeling is in compliance with OTC labeling requirements set forth in 21 CFR 201.66. The third labeling sample illustrates the proposed format and text as an outcome of the requested exemptions. The proposed labeling differs from the requirements but fulfills the basic need to provide labeling that addresses potential safety issues and to ensure selection of the most appropriate product. The general rationale for the exemptions requested is provided in Section I of this submission and the complete list of exemptions requested is provided in a table in Section II.

In summary, Whitehall-Robins supports the agency's efforts to provide the consumer with OTC drug labeling that is easier to read and understand. However, we request this exemption for the Chap Stick skin protectant lip balm products because the information can be presented with less complexity on the labeling and still communicate appropriate and safe use of the products.

Sincerely,

WHITEHALL-ROBINS HEALTHCARE



Hulon W. McCain, Ph.D
Director, Regulatory Affairs

Cc: Charles J. Ganley, M.D. (Director, Division of Over-the-Counter Drug Products)
Gerald M. Rachanow (Division of Over-the-Counter Drug Products)

Whitehall-Robins Healthcare

**Application for Exemption
From OTC Labeling Format (21 CFR 201.66)**

Docket No. 98N-0337

September 11, 2000

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I. Introduction and General Rationale for Exemptions Requested

Whitehall-Robins Healthcare (Whitehall-Robins) recognizes the need for providing consumers with OTC drug labeling that is easy to understand and, therefore, agrees with the FDA's ruling as outlined in the March 17, 1999 Federal Register for labeling OTC drug products. However, for products marketed in small packages that contain ingredients intended to provide a therapeutic effect and provide favorable public health benefits to consumers, the final rule for OTC labeling is impracticable and inapplicable.

Loose sticks and tubes account for a significant portion of Chap Stick sales. Key retailers maintain "front-end" lip balm merchandising which provides consumer convenience and accounts for recent increases in retail sales of up to 70%. Placement at the front-end of stores also provides convenience to the customer. Quantitative research indicates that consumers expect to find lip balms at the "front-end" of retail outlets. Loose sticks and tubes are necessary in order to gain "front-end" or checkout placement at these retail outlets. Retailers allow limited blister carded product placement at the front-end due to limited retail space. Inability to produce loose sticks and use of mandated blister cards would result in significant loss of front-end sales volume, and consumer convenience.

We agree that labeling should be in compliance with 21 CFR 201.66 when these products are sold with an outer blister card or carton. However, we request that the agency provide an exemption for the Chap Stick line of skin protectant lip balm products that are available on the market in loose sticks, without a blister card outer package.

We believe the final rule for OTC labeling is *impracticable* for the Chap Stick lip balm products as the available labeling space (2.8 square inches) on the stick is not adequate for the amount of required information (Drug Facts and PDP requirements). Various labeling designs were evaluated in effort to comply with all provisions under the current Drug Facts final rule. The cap label space was also considered but was found to be unacceptable for labeling because of its shape and size. The small size and cylindrical shape of the cap would not enable an accurate bar code reading at checkout and it does not provide adequate space for text readability.

We believe that portions of the final rule should be deemed *inapplicable* to the Chap Stick products, as skin protectant lip balms need minimal information for the safe and effective use of the product. As stated in 64 FR 13254 at 13270 (March 17, 1999 ruling for OTC Drug Products Labeling Requirements), these products are packaged in small containers, have a high therapeutic index, carry extremely low risk in consumer use situations, provide a favorable public health benefit, and require few specific warnings.

The Chap Stick skin protectant lip balms (.15 oz stick) help prevent and protect chafed, chapped, cracked, or windburned lips. The products carry an extremely low risk for consumer use because the active and inactive ingredients, commonly used in OTC drug and cosmetic products for several years, have an established safety profile. The availability of a small package size at the checkout counter provides a convenience to

consumers for purchasing a product that offers a favorable benefit for lip care. Because there are few specific warnings, the required information can be presented with less complexity on the labeling and still communicate appropriate and safe use of the product.

II. List of Exemptions Requested for Lip Balms with Skin Protectant as the only Active Ingredient

21 CFR Reference	Description of Requirement	Description Of Exemption	Rationale for Exemption
201.66 (d) 8	Drug Facts in a box or similar enclosure. Horizontal hairlines and barlines separate sections.	Omit box and lines as permitted for sunscreen products 21 CFR 352.52 (f) (2)	Small package exemption for products labeled for use only on specific small areas of the face
201.66 (c) (1)	Title: Drug Facts and Drug Facts (continued)	Omit as permitted for sunscreen lip balms – 21 CFR 352.52 (f) (1)	Small package exemption for products labeled for use only on specific small areas of the face
201.66 (c) (3)	The heading “ <i>Purpose</i> ” flush right of the heading “ <i>Active ingredients</i> ”. Purpose for each active ingredient listed under the heading.	Omit as permitted for sunscreen lip balms – 21 CFR 352.52 (f) (1)	Small package exemption for products labeled for use only on specific small areas of the face
201.66 (c) (5) (x)	Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away	Omit “swallow” warning as permitted for sunscreen lip balms 21 CFR 352.52 (f) (1) (v)	Small package exemption for products labeled for use only on specific small areas of the face
201.66 (d) (6)	“ <i>Active ingredient</i> ” heading and information in (c) (2) shall be left justified. Active ingredients shall be aligned and left justified under the heading “Active ingredient”.	Allow ingredient to follow “ <i>Active ingredient</i> ” heading on same line instead of on the next line	Spacing between ingredient and heading allow adequate readability. Bold, italics, and type size provide adequate prominence of “ <i>Active ingredient</i> ” heading
201.66 (d) (6)	None of the information in (c) (5) shall follow on the same line as “ <i>Warning</i> ” or “ <i>Warnings</i> ”	Allow statement to follow “ <i>Warning</i> ” heading on same line	Bold, italics, and type size provide adequate prominence of “ <i>Warning</i> ” heading
201.66 (c) (6)	Directions for use	Omit “ <i>Directions</i> ” section	21 CFR 201.116 states “A drug shall be exempt from section 502(f)(1) of the act insofar as adequate directions for common uses thereof are known to the ordinary individual.” Chap Stick identity and “Uses” provide adequate information to enable correct application of the product
201.66 (c) (8)	“ <i>Inactive ingredients</i> ” followed by a listing of the established name of each active ingredient	Omit “Inactive ingredients” section	Allow space for the bar code (mandatory for the retailer)

III. Justification for Exemptions Requested

The exemptions requested can be grouped into the following categories:

A. Small Package Lip Balm

The final rule for Sunscreen OTC drug products provides a small package exemption in 21 CFR 352.52 (f) for products intended for use only on specific small areas of the face (eg. lips). The Chap Stick skin protectant lip balms also meet the basic requirements set forth in 21 CFR 352.52 (f). Details of these requirements and the 4 related exemptions are provided in the table in Section II of this submission.

B. Format

Because of the small amount of label space and the cylindrical shape of the small container the important information is read in a very narrow (width and length) visual area. An exemption from the format requirements set forth in 21 CFR 201.66 (d)(6) and (7) would allow text to start on the same line as the headings "***Active ingredient***" and "***Warnings***". This would provide a more even flow of information in the small visual area for the lip balm tube or stick containers. Prominence of the headings is adequately presented by the bold, italics, and larger type size.

C. Text Omission

Justification for omission of "***Directions***" is provided in 21 CFR 201.116, which states "A drug shall be exempt from section 502 (f)(1) of the act insofar as adequate directions for common uses thereof are known to the ordinary individual." The Chap Stick lip balm identity and the statements in "Uses" provide adequate information to enable correct application of the product.

Omission of the "***Inactive ingredients***" section allows space for the bar code (mandatory for retail) to be printed on the stick. The size of the bar code cannot be smaller until technology is upgraded. The bar code cannot be printed on the cap because the small cylindrical shape makes it impossible for scanning at the checkout counter.

Loose sticks are customarily available in an open bin or dispenser and placed conveniently on or near the counter at the checkout section of retail stores. If necessary, inactive ingredients could be listed on the dispenser carton at point of purchase.

IV. List of Products Currently Effected

Chap Stick Lip Balm Products Containing Only Skin Protectant Active
Ingredients

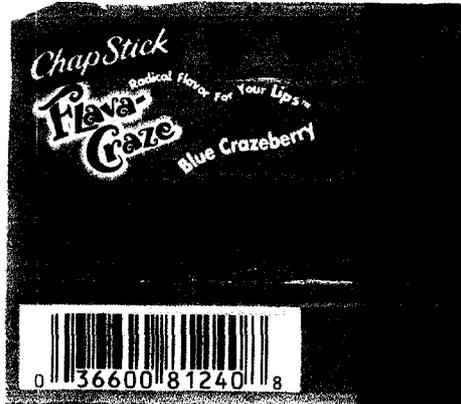
<u>Product Name</u>	<u>SKU</u>
Flava-Craze Grape Craze	Stick .15 oz
Flava-Craze Blue Crazeberry	Stick .15 oz
Flava-Craze Fruit Craze	Stick .15 oz

V. Sample Labeling (Skin Protectant Lip Balms)

A. Current Labeling for Flava Craze Blue Crazeberry

Stick

Cap



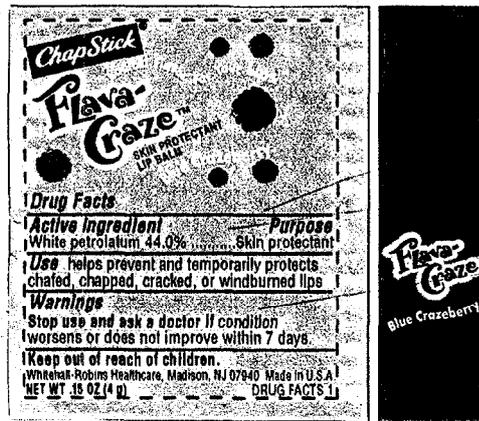
LEGAL TEXT DEFINED	SIZE
• HEADINGS	5.00pt
• SUBHEADINGS	NA
• TEXT	5.00pt
• BULLETS	NA

V. Sample Labeling (Skin Protectant Lip Balms)

**B. Drug Facts Compliant Labeling for Flava Craze Blue Crazeberry
 in compliance with Drug Facts format, 21 CFR 201.66**

Stick

Cap



Drug Facts Requirement

Modified format with barlines and hairlines and contrasting background

Text on contrasting background

Headings:

7 point Helvetica Bold, Italic, left justified

Subheadings: Bold Regular, 6 point Helvetica

Body text: 6 point Helvetica, Regular

Information may start on same line as headings (except Warnings) and subheadings

Exemptions Requested*

Omit Drug Facts Title, Purpose section, hairlines, and barlines as permitted by 21 CFR 352.52(f) for sunscreen lip balms

Active ingredient to immediately follow the heading on the same line.

Information to start on same line as "Warning" heading

Omit "swallow" warning as permitted by 21 CFR 352.52(f) for sunscreen lip balms

Omit Directions as permitted by 21 CFR 201.116

Omit Inactive ingredients

Text Overflow

Directions apply liberally as often as necessary

Inactive Ingredients

arachidyl propionate, cetyl alcohol, FD&C Blue No. 1 Aluminum Lake, flavors, isopropyl lanolate, isopropyl myristate, lanolin, light mineral oil, methylparaben, octyldodecanol, phenyl methicone, propylparaben, saccharin, waxes



Bar Code is mandatory on the product labeling of loose sticks for appropriate identification at the retailer. It can be no smaller until technology is upgraded.

LEGAL TEXT DEFINED BY 21 CFR 201.66(d)(10)	SIZE
• TITLE	7.1pt
• HEADINGS	7.00pt
• SUBHEADINGS	6.00pt
• TEXT	6.00pt
• BULLETS	5.00pt
• RULES	.8 + .5

*See Section II for the CFR reference and rationale for each specific exemption.

V. Sample Labeling (Skin Protectant Lip Balms)

C. Drug Facts Modified Label (Proposed Labeling) for Flava Craze Blue Crazeberry.
 Required text with requested exemptions.

Stick

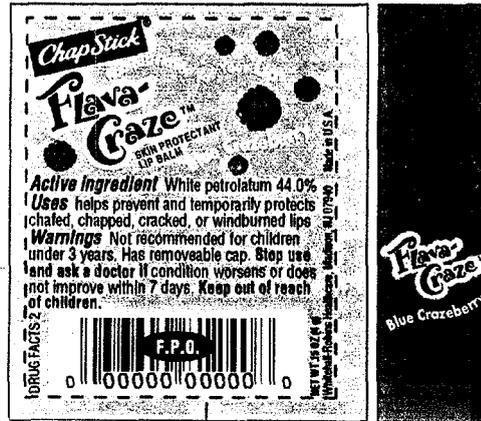
Cap

Modified format with contrasting background and no enclosure lines

Headings:
 7 point Helvetica, Bold. Italics, left justified

Information may start on same line as headings and subheadings

Subheadings 6 point Helvetica, Bold, left justified



Body text: 6 point Helvetica, Regular

Text on contrasting background

Bar Code is mandatory on the product labeling of loose sticks for appropriate identification at the retailer. It can be no smaller until technology is upgraded.

Note: Omission of "Drug Facts" title, Purpose section, hairlines, and barlines as permitted by 21 CFR 352.52(f) for sunscreen lip balms

LEGAL TEXT DEFINED	21 CFR 201.66(d)(10) SIZE	PROPOSED REVISION SIZE
• HEADINGS	7pt	7 pt
• SUBHEADINGS	6pt	6 pt
• TEXT	6pt	6 pt
• BULLETS	5pt	NA
• LINES	.5pt	NA