The Most Common Mistakes Made In Labeling Sunscreens

David C. Steinberg, FRAPS
Steinberg & Associates, Inc.
January 28, 2014
Disclaimer

• I am unaware of any regulatory action being taken by the FDA over these mistakes.
• I purchased or took pictures of these this year so they should be compliant.
• I did not look for errors.
• I am not a good photographer!
• I will pick on 1 label as they should have known better!
smashbox camera ready CC CREAM
BROAD SPECTRUM SPF 30
DARK SPOT CORRECTING
Common Errors - The Front

• You must have the word **Sunscren** somewhere on the front of the label.

• You cannot list other methods of rating UVA
  etc.)
smashbox camera ready CC CREAM BROAD SPECTRUM SPF 30
DARK SPOT CORRECTING
CRÈME BONNE MINE SPF15

Raffermit, Corrige les rides
Acide hyaluronique & Resveratrol-Oleyl 750

BROAD SPECTRUM SPF15
RADIANCE DAY CREAM

$75
Front Using Unapproved UVA Claims
Next Error
• The words **Broad Spectrum** and **SPF and Number** must be continuous with no interruptions and of the same style and size.
NEW

OLE HENRIKSEN

all skin types/anti-aging

protect the truth™ SPF 50+
broad spectrum
UV protection with Solar Active Complex™
Australian Gold

Sheer Coverage with InvisiDry™ Technology

Very Water Resistant Sunscreen
Clean and Hydrating
Broad Spectrum
UVA/UVB Protection

177 mL / 6 Fl. Oz
Hydratant matifiant 8h SPF 20
8hr Mattifying moisturizer sunscreen
stop shine, not moisture
broad spectrum SPF 20

Testé dermatologiquement
Dermatologically tested / Oil-free
50 ml 1.69 fl.oz.
Stays on Strong when you Sweat
(won't run into eyes and sting)
CC CREAM
broad spectrum
SPF 30
COMPLEXION CORRECTOR
COMPOSER DE COMPLEXION
anti-aging
sunscreen
complexion
corrector &
tint in one
help
protect
brighten &
maintain
moisturize
camu camu &
arbutin
help
improve
the appearance of
uneven skin tone
Next Error
Net Contents

• **Metric** only or **Metric** must be first

• Correct abbreviations:
  – g
  – mL
  – Fl. Oz.
  – Oz.
30

8 FL OZ (237 mL)

38584-FA
Reduces the look of expression lines and deep wrinkles

1.0 fl oz (30 mL)
Illegal Claims

- PABA-Free
- Sunblock
- Waterproof
PABA Free

Drug Facts

Active ingredients
Avobenzone 2.7%, Homosalate 8%, Octisalate 5%, Octocrylene 3.5%, Dicaprylyl 4%

Purpose
Sunscreen

Uses
• Helps prevent sunburn • If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings
• For external use only • Do not use on damaged or broken skin • When using this product keep out of eyes. Rinse with water to remove • Stop use and ask a doctor if rash occurs • Keep out of reach of children • If swallowed, get medical help or contact a Poison Control Center right away

Directions
• Apply generously 15 minutes before sun exposure • Reapply after 80 minutes of swimming or sweating • Immediately after towel drying • At least every 2 hours • Sun Protection Measures: Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including • Limit time in the sun, especially from 10 a.m. – 2 p.m. • Wear long-sleeved shirts, pants, hats, and sunglasses • Children under 6 months of age: Ask a doctor

Other Information
• Protect this product from excessive heat and direct sun • May stain some fabrics

Inactive Ingredients
Water, di-
Sunblock-Waterproof
Drug Facts Errors

- Incorrect Drug Facts Information
- Incorrect capitalization
- Missing critical information
Run-on Actives

**Drug Facts**

<table>
<thead>
<tr>
<th>Active ingredients</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avobenzone 3%, Homosalate 15%, Octisalate 5%, Octocrylene 10%, Oxybenzone 6%</td>
<td>Sunscreen</td>
</tr>
</tbody>
</table>

**Uses**
- Helps prevent sunburn
- If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun

**Warnings**
- For external use only
- Do not use on damaged or broken skin
- When using this product keep out of eyes. Rinse with water
Run-on Bullets
Drug Facts

Active ingredients
Avobenzone 3%, Homosalate 15%, Octisalate 5%, Octocrylene 10%, Oxybenzone 3%

Purpose
Sunscreen

Uses
• helps prevent sunburn • if used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings
• For external use only • Do not use on damaged or broken skin • When using this product, keep out of eyes. Rinse with water to remove. • Stop use and ask a doctor if irritation occurs

Proper use
• Avoid contact with eyes, lips, and mucous membranes • Aloe vera base • ensure complete coverage to the nose, lips, scalp, nose, and tops of ears • Reapply: • after 80 minutes of swimming or sweating • immediately after towel drying • at least every 2 hours • Sun Protection Measures: Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including: • limit time in the sun, especially from 10 a.m. to 2 p.m. • wear long-sleeved shirts, pants, hats, and sunglasses • children under 6 months of age: Ask a doctor

Other information
• protect this product from excessive heat and direct sun • may stain some fabrics • package contains small parts, which could cause a choking hazard

Inactive ingredients
adipic acid/diglycol crosspolymer, beeswax, BHT, UFA-15 alkyl benzene, diethylhexyl 2,6-naphthalate, dimethicone, fragrance, neopentyl glycol diphthalate, neopentyl glycol diisostearate, octyldodecyl neopentanoate, octyldodecyl polyethylene

Questions or comments? Visit www.neutrogena.com or call toll-free 800-326-3787 or 315-273-8785 (collect)

© 2015 M.R. LIPTON Co. Neutrogena Corporation, Los Angeles, CA 90045 Made in Canada
Run On Bullets

• If Drug Facts take up more than 60% of the label for FDA required information; you can use a modified format but you must not consider any advertising text for the 60%:
  – Box not required
  – May use less than 0.5 point leading
  – Drug Facts must be a minimum of 7 point
  – Headings 1 point smaller
  – Text 1 point smaller than headers
  – Bullets can run on but must be separated by 2 EM spaces
Other Conditions for 60% Rule

No Optional text is allowed

Uses Section
• If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun.

Directions Section
• apply to all skin exposed to the sun

Questions Section
Not allowed
No Background on Drug Facts
Fine Lines Do Not Touch
No Capitol “I” in ingredients
Drug Facts
Active Ingredients
- Avobenzone 2.0%
- Octocrylene 5.0%
- Oxybenzone 3.0%

Purpose
Sunscreen

Uses
- Protects against sunburn
- If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings
- For external use only
- Do not use on damaged or broken skin
- When using this product keep out of eyes. Rinse with water to remove
- Stop use and ask a doctor if rash occurs
- Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away

May stain some fabrics

Directions
- Apply liberally 15 minutes before sun exposure
- Reapply after 80 minutes of swimming or sweating
- Immediately after towel drying
- Sun Protection Measures: Spending time in the sun increases the risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures, including: limit time in the sun, especially from 10 a.m. to 2 p.m., wear long-sleeve shirts, pants, hats, and sunglasses
- Children under 6 months: Ask a doctor

Inactive Ingredients
- Water, Ethylhexyl Benzate, Glycerin, VP/Hexene Copolymer, Cetearyl Alcohol, Diisopropyl Adipate, Isopropyl Myristate, Isostearalkohol, Phenoxyethanol, Polyacrylates, Acrylates Copolymer, Caprylyl Glycol, Dimethicone, Poloxamer, Triethanolamine, Glycerin, Phosphates, Xanthan Gum, Carbomer, Disodium EDTA, Mineral Oil, Butyrospermum Parkii (Shea) Butter, Sodium Ascorbyl Phosphate, Tocopheryl Acetate, Aloe Barbadensis Leaf Juice, Panthenol, Phenoxyethanol, Methysetsenyl, Propylparaben, Iron Oxides, Chromium Hydroxide Green

Other Information
- Protect this product from excessive heat and direct sun

Questions or Comments?
Call 1-800 SafeSun, Mon-Fri

*For sun protection, use as directed

www.bonanaboat.com

Dir. By: Energizer Personal Care

©2012 Sun Pharmacuticals
MADE IN U.S.A.
Incorrect Inactive Ingredient Words

Inactive ingredients: water, butylene glycol, microcrystalline cellulose, glyceryl stearate, behenyl alcohol, benceyl alcohol, dioctyl sebacate, tocopherol (vitamin E), retinyl palmitate (vitamin A), sodium ascorbyl phosphate, stearic acid, palmitic acid, lauryl alcohol, myristyl alcohol, cetyl alcohol, lecithin, fragrance, chlorophenesin, cellulose gum, butylated PVP, disodium EDTA.

Questions? 866-266-3330
Drug Facts (Continued)

Inactive Ingredients
Water/Eau, C12-15 Alkyl Benzoate, Cyclotetrasiloxane, Polyethylene Resinate, Cyclopentasiloxane, Aluminum Starch Octenylsuccinate, Butylene Glycol, Sorbitan Sesquioleate, Dimethicone, Isostearic Acid, Cyclpentasiloxane, Phenyl Trimethicone, Cetyl PEG/PPG-10/1 Dimethicone, Ceramide 3, Ceramide 6-II, Ceramide 1, Niacinamide, Cholesterol, Phytosphingosine, Sodium Hyaluronate, Disteardimonium Hectorite, Phenoxyethanol, Magnesium Sulfate, Sodium Chloride, Polyhydroxystearic Acid, Sodium Polyacrylate, Propylene Carbonate, Triethoxycaprylylsilane, PEG/PPG 18/18 Dimethicone, Ethylhexylglycerin, Trideceth-6, Sodium Lauroyl Lactylate, Carbomer, Xanthan Gum.

Other Information
- Protect this product from excessive heat and direct sun.

Questions?
Toll-free number (800)-321-4576
www.CeraVe.com
Alphabetical Listing of Inactives

• Permitted if no cosmetic claims are made and must be USAN names (USP).

• I never saw a commercial sunscreen that
Drug Facts

Active ingredients
Avobenzone 3%, Homosalate 15%, Octisalate 5%, Octocrylene 10%, Oxybenzone 3%

Purpose
Sunscreen

Uses
• helps prevent sunburn • if used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings
• For external use only • Do not use on damaged or broken skin • When using this product, keep out of eyes. Rinse with water to remove • Stop use and ask a doctor if irritation occurs

Directions
• Apply generously and evenly on areas exposed to the sun • Reapply if swimming, sweating, or after sun exposure • Sunburn protection: Apply 15 minutes before sun exposure. Wear protective clothing and stay in shade • Sun Protection Measures: Spend time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including: limit time in the sun, especially from 10 a.m. to 2 p.m. wear long-sleeved shirts, pants, hats, and sunglasses • children under 6 months of age: Ask a doctor

Other Information
• protect this product from excessive heat and direct sun • may stain some fabrics • package contains small parts, which could cause a choking hazard

Inactive ingredients
adipic acid/diglycol crosspolymer, beeswax, BHT, Urea, D异thiodiglycol, diethylhexyl 2,6-naphthalate, dimethicone, fragrance, neopentyl glycol distearylate, neopentyl glycol diisostearate, octyldodecyl neopentanoate, octacosyl, palmitate, polyethylene

Questions or comments? Visit www.neutrogena.com or call toll-free 1-800-288-7799 or 213-273-8755 (collect)

© 2008 by Neutrogena Corporation, Los Angeles, CA 90045 Made in Canada
Correct USAN Names

• Butylated Hydroxytoluene
• Ok as labeled
  – Dimethicone
  – Paraffin
• Not listed-therefore not permitted
  – All the rest!
• Cosmetic claims on the back include
  • Oil free
  • Non comedogenic
  • Hypoallergenic
Incorrect Placement of Drug Facts

CeraVe®
DEVELOPED WITH DERMATOLOGISTS

Sunscreen
BROAD SPECTRUM SPF 30

FACE LOTION SPF 30

InvisibleZinc™
Lightweight, and oil-free
Water resistant (80 minutes)

With ceramides, zinc oxide and hyaluronic acid

Net Wt. 2.5 OZ (70 g)
Front and 1 Side
Developed with dermatologists, CeraVe Sunscreen for Face SPF 30 is like no other sunscreen you’ve ever experienced. Enjoy powerful protection from the same zinc oxide trusted by lifeguards and dermatologists, now in a new lightweight formula that spreads easily and dries with a clear finish.

- Ceramides help repair and restore the protective skin barrier
- Niacinamide helps the skin produce more natural ceramides and fatty acids essential for repairing and restoring the skin barrier. May also reduce skin redness.
- Hyaluronic acid attracts moisture to the top layer of the skin.

High performance, water-resistant, suitable for all skin types. CeraVe Sunscreen is perfect for daily use for even the most sensitive skin.

INVISIBLE ZINC™ technology uses a revolutionary naturally sourced micro-fine zinc oxide to deliver its unique dry, clear finish for powerful protection from the sun’s damaging rays.
Problems

• Drug Facts must be on the back first and than extended to the sides

• Arrows are needed to tell consumers where to continue looking

• Drug Facts takes predominance over advertising copy.
Ampersand Labels
Consumers Have the Right To See Drug Facts Before Purchasing
The Most Dangerous Error

- Listing an active ingredient and the same chemical as an inactive ingredient.
- Mostly Titanium Dioxide in make-up/SPF products.
- Use of Pigment size and Micro size for different purposes.
- How does the chemical know what it is suppose to do?
Continued

• You product will fail stability testing as this is run on total Titanium dioxide present.

• You will need to prove that the inactive amount of Titanium dioxide does not add 2 SPF units.

• You raise the question that they are different.
Finally

- The FDA says they are the same and has no issues on their safety.

- This may force the FDA to look at this, resulting in the only currently permitted grade for sunscreens is pigment size.

- You will be ostracized if this happens!
The Worst Example

• Can you spot all the errors?

• I found 7 major errors
Sunscreen Labeling According to 2011 Final Rule

If used as directed with other sun protection measures, this product reduces the risk of skin cancer and early skin aging, as well as helps prevent sunburn.

Only products labeled with both "Broad Spectrum" AND SPF15 or higher have been shown to provide all these benefits.

Drug Facts

Active Ingredients
- Avobenzone 3%
- Homosalate 10%
- Octyl methoxycinnamate 7.5%

Purpose: Sunscreen

Uses
- Helps prevent sunburn
- If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings
For external use only
- Do not use on damaged or broken skin
- When using this product keep out of eyes. Rinse with water to remove.
- Stop use and ask a doctor if rash occurs
- Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions
- Apply liberally 15 minutes before sun exposure.
- Reapply:
  - After 40 minutes of swimming or sweating
  - Immediately after towel drying
  - At least every 2 hours
- Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including:
  - Limit time in the sun, especially from 10 a.m. - 2 p.m.
  - Wear long-sleeve shirts, pants, hats, and sunglasses
  - Children under 6 months: Ask a doctor

Inactive ingredients
- Aloe extract, barium sulfate, benzyl alcohol, carbomer, dimethicone, disodium EDTA, jojoba oil, methylparaben, octodecenoic acid, copolymer, polyglyceryl-3 distearate, phenoxyethanol, propylparaben, sorbitan isostearate, sorbitol, stearic acid, tocopheryl (vitamin E), triethanolamine, water

Other information
- Protect this product from excessive heat and direct sun

Questions or comments?
Call toll free 1-800-XXX-XXXX
What the FDA Did Wrong

• Front
  – Metric not first
  – Incorrect abbreviations for contents
Drug Facts

• Failure to use drug names for active ingredients

• Use of brackets are not permitted

• Inactive ingredients not found in USP/USAN

• Failure to comply with PL 109-462
Correct Name

• Octinoxate is the correct drug name not what they put down-Octyl methoxycinnamate.

• Շնուկարենի տատարեր/ Lyt Y Şe
Brackets

• You can use running ants

• You can repeat the word Sunscreen or use ditto marks
inactive ingredients

- aloe extract, barium sulfate, benzyl alcohol, carbomer, dimethicone, disodium EDTA, jojoba oil, methylparaben, octadecene/MAcopolymer, polyglyceryl-3 distearate, phenethyl alcohol, propylparaben, sorbitan isostearate, sorbitol, stearic acid, tocopherol (vitamin E), triethanolamine, water
USP/USAN

FDA
• Aloe extract
• Barium sulfate-ok
• Benzyl alcohol-ok
• Carbomer
• Dimethicone-ok
• Disodium EDTA
• Jojoba Oil
• Methyparaben-ok

Correct Name
• Aloe (but extract does not meet specifications)
• Must have the number
• Edetate Disodium
• Not listed
Continued

FDA
• octadecene/MA copolymer
• polyglyceryl-3 distearate
• phenethyl alcohol-ok
• Propylparaben-ok
• sorbitan isostearate
• sorbitol

Correct Name
• Not listed (Octadecene/MA Copolymer is correct INCI name)
• Not listed
• Not listed
• Sorbitol Solution
Continued

FDA
• Stearic acid-ok
• tocopherol (vitamin E)
• Triethanolamine
• Water

Correct Name
• Tocopherol
• Trolamine
• Purified water
PL 109-462

- A way for consumers to report serious adverse reactions are now required for all OTC drugs since 2006-8.
  - Phone number must be answered 24/7/365 by a human being who can give medical advice.
  - Address is preferred-must be in United States.
  - Under Other information in Drug Facts is the best location.

- Must be clearly labeled for this to be compliant:
  - You may report a serious adverse reaction to this product to …….
“Okay, okay, okay... everyone just calm down and we'll try this thing one more time.”
Commercial

• A Strategic Alliance has been established between Steinberg & Associates, Inc and NSF International

• Free Webinar February 13 at 2pm EST on State of the Cosmetic Industry
  – Data Facts
  – FDA Draft guidance on Anti-bacterial cleansers
  – Claims
• To register:http://www.nsf.org/training-education/training-entry/free-webinar-state-of-the-cosmetics-industry-what-you-should-know-to-better
Questions?

David C. Steinberg
Steinberg & Associates, Inc.
Report Reaction, LLC
609-799-1575 phone
609-799-5271 fax
davidpreserve@comcast.net
Thank You!