FDA Docket No. FDA-2015-D-4021

OCT 20, 2016

MEETING MINUTES

Personal Care Products Council
Attention: Thomas Myers
General Counsel
1620 L Street, NW
Suite 1200
Washington, DC 20036

Dear Mr. Myers:

Please refer to your April 27, 2016 correspondence, requesting a meeting to discuss sunscreen formulations.

We also refer to the meeting held between Personal Care Products Council and FDA on September 7, 2016.

A copy of the official minutes of the meeting is enclosed for your information. Please notify us of any significant differences in understanding regarding the meeting outcomes.

If you have any questions, call Kristen Hardin, Regulatory Project Manager at (240) 402-4246.

Sincerely,

[Signature]
Theresa Michele, MD
Director
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE: Meeting Minutes
Memorandum of Meeting Minutes

Date: September 7, 2016
Time: 2:30–4:00 p.m.
Location: 10903 New Hampshire Avenue
          White Oak Building 22, Conference Room 1419
Meeting Chair: Theresa Michele, MD
Meeting Recorder: Kristen Hardin, BSN, RN

FDA ATTENDEES

Office of Drug Evaluation IV
Charles Ganley, Director
Lesley Furlong, Deputy Director
Jagjit Grewal, Associate Director of Regulatory Affairs
Jian Wang, Staff Fellow
Jennifer Shing, ORISE Fellow

Division of Nonprescription Drug Products
Theresa Michele, Director
Kristen Hardin, Regulatory Project Manager
Brenda Gierhart, Medical Reviewer
Jane Sohn, Pharmacology/Toxicology Team Lead
Jennifer White, Pharmacology/Toxicology Reviewer
Steven Adah, Interdisciplinary Scientist Team Lead
Arlene Solbeck, Interdisciplinary Scientist
Sergio Coelho, Interdisciplinary Scientist
Diego Rua, Interdisciplinary Scientist
Stephanie Daniels, ORISE Fellow

Office of New Drug Products
Eric Duffy, Director
Swapan De, Chemistry, Manufacturing and Controls Team Lead

Division of Clinical Pharmacology III
Dennis Bashaw, Director
Luke Oh, Senior Staff Fellow
Sojeong Yi, Staff Fellow
Office of Regulatory Policy
Jane Baluss, Senior Regulatory Counsel
Sharon Coleman, Senior Regulatory Counsel

SPONSOR ATTENDEES

Personal Care Products Council
Thomas Myers
Beth Jonas
Emily Harp Manoso
Lauren Brady
Linda Loretz

Consumer Healthcare Products Association
Jay Sirois

Bayer
Eduardo Ruvolo
Monica Hug

Edgewell
Kathleen Edgar
Grace Riccardi

Johnson & Johnson
Susan Daly
Prithviraj Maitra
Christina Jessurun Thomas

Procter & Gamble
Sally Vater
J Nash
Paul Matts
Paul Tanner

L'Oreal
John Tomaszewski

International Cosmetics
Janet Blaschke
1.0 BACKGROUND

On April 27, 2016, the Personal Care Products Council (Council) and the Consumer Healthcare Products Association (CHPA), through the joint Sunscreen Task Force, requested a meeting to discuss several technical questions posed by FDA during a September 29, 2015 discussion at FDA’s White Oak Campus. To address FDA’s questions, the Council requested this September 7, 2016 meeting.

The sponsor’s questions from the meeting package are in **bold** font. Highlights of the meeting discussion are in normal font.

2.0 DISCUSSION

The Council initiated the meeting with a detailed presentation on sunscreen formulation development. The presentation included discussion of topics such as how sunscreens work, the formulation of sunscreen products, efficacy and test methods, skin penetration, and safety evaluation.

At the conclusion of the slide presentation, the Council requested that FDA provide a response to the following questions.

1. The Sunscreen Innovation Act (SIA) established for FDA to finalize the monograph by November 26, 2019. FDA previously informed industry that the agency would publish a proposed rule, prior to finalizing the monograph, which would include topics such as ingredients, dosage forms and SPF. We heard from the agency that the objective of this interim rule making action is to ignite additional dialogue with stakeholders via a public comment period. As an industry we would like to ensure we are well prepared for any opportunity such an interim rule making action would offer for submitting comments that are based in sound science, which will require preparation and time.

When we met 12 months ago, Dr. Michelle indicated that Congress expects FDA to address all issues in the Monograph or to provide a rationale for those not included.

Is it still your expectation that a Final Monograph will include final actions on active ingredients, dosage forms and maximum SPF? If there are questions for which industry expertise would be helpful, we are open to assisting the Agency in any way we can.

FDA Response to Question 1:
Yes, this is our expectation.

2. In our meeting in September 2015, FDA stated that it would take a minimum of two years to write a Final Monograph and get it through inter-agency and OMB review, which means November 2017. Therefore, a revised TFM would need to be published no later than early 2017. Does FDA intend to add this rulemaking to the FDA Federal Agenda?
FDA Response to Question 2:
The final rulemaking will be placed on the Unified Agenda.

3. A Final Rule on Testing and Labeling was published in June 2011; however, the agency has recently asked numerous questions about the test methods. Does the agency intend to include changes to the test methods in the Final Monograph? Specifically, is FDA considering harmonizing the SPF/Water Resistance and UVA methods in accordance with International Monographs methods?

FDA Response to Question 3:
If data is submitted during the course of rulemaking in support of a request to revise the current test methods, the agency will consider that data prior to issuing the Final Monograph.

3.0 ACTION ITEMS

None.

4.0 ATTACHMENTS AND HANDOUTS

The Council’s presentation on sunscreen formulation is attached.
Sunscreen Formulation

A presentation to the FDA by the Personal Care Products Council

7th September 2016
Mission of PCPC Sunscreen Committee

• To provide the personal care industry with guidance on sunscreens and related matters

• To maintain and strengthen our relationship with relevant experts working at FDA, clinical settings, and in industry,

• To actively monitor and appropriately engage in current and emerging science, regulations and standards that may impact the marketing of sunscreen products,

• To actively collaborate with national and international standard-setting organizations in establishing sunscreen test methods,

• To respond to scientific and regulatory issues arising in the literature and / or media concerning sunscreens.
Agenda

• How Sunscreens Work
• Formulation of sunscreen products
• Efficacy and test methods
• Skin penetration and safety evaluation
• Summary and Conclusions
• Q&A
Executive Summary

1. Effective sunscreen formulation is based on scientific first-principles and subject to boundaries imposed by photochemistry and photobiology.

2. While sunscreens have multiple different forms, the underlying principle driving effective photo-protection is the same – creation of an homogeneous distribution of UV filters on the skin surface to reduce UVR exposure.

3. Sunscreen efficacy is determined by product form, the sunscreen active system and effective formulation.

4. Safety assurance is based on widely accepted approaches and within the framework of the Sunscreen Monograph.
How sunscreens work – reducing the flux (and cumulative dose) of UVR photons to the skin.

Organic (solubilised)

Inorganic (particulate)

Singlet

Triplet

UVR

Heat
Formulation of sunscreen products

- Step 1: Product idea
- Step 2: Product form
- Step 3: Sunscreen active system (UV filters)
- Step 4: Vehicle optimization
Formulation of sunscreen products (1)

• **Product idea**

  – What is the “job” to be done?
    • Recreational / sport
    • Daily care (e.g., moisturization)
    • Color cosmetic
    • Lip care

  – Global vs regional

  – Market positioning / cost
Formulation of sunscreen products (2)

• Product forms in today’s market-place
  – Emulsion (lotion / cream)
  – Spray
  – Stick
  – Powder
Example of product architecture – Emulsion (o/w)

Note: these are specific worked examples – form architecture may vary across labs / formulators.
Example of product architecture – Spray

- Ethanol
- UV Filters
- Film Formers
Example of product architecture – Stick

- Emollients
- UV Filters
- Thickeners
- Film Formers
- Preservative
Irrespective of sunscreen form, all products are designed with a primary objective – to leave an homogeneous protective film on the skin surface.
Formulation of sunscreen products (3)

• Sunscreen active system – key considerations
  
  – Regulatory status?
  – SPF target (amplitude of protection)?
  – Broad-spectrum (UVA; breadth of protection)?
  – Water-resistance?
  – Efficiency (e.g., efficacy, aesthetics)?
  – Cost?
### UVR absorption profiles for the most commonly-used UV filters

<table>
<thead>
<tr>
<th>UV Filter</th>
<th>Conc. (%)&lt;sup&gt;1&lt;/sup&gt;</th>
<th>UV Attenuation (nm)&lt;sup&gt;2&lt;/sup&gt;</th>
<th>Peak Absorbance Wavelength (nm)</th>
<th>Critical Wavelength (nm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PBSA (2-phenylbenzimidazole-5-sulfonic acid)</td>
<td>4</td>
<td></td>
<td></td>
<td>324&lt;sup&gt;3&lt;/sup&gt;</td>
</tr>
<tr>
<td>OSAL (octyl salicylate)</td>
<td>5</td>
<td></td>
<td></td>
<td>327</td>
</tr>
<tr>
<td>HSAL (homosalate)</td>
<td>15</td>
<td></td>
<td></td>
<td>328</td>
</tr>
<tr>
<td>OPABA (octyldimethyl PABA)</td>
<td>8</td>
<td></td>
<td></td>
<td>330</td>
</tr>
<tr>
<td>OMC (octyl methoxycinnamate)</td>
<td>7.5</td>
<td></td>
<td></td>
<td>339</td>
</tr>
<tr>
<td>OCTO (octocrylene)</td>
<td>10</td>
<td></td>
<td></td>
<td>356</td>
</tr>
<tr>
<td>OXY (oxybenzone)</td>
<td>6</td>
<td></td>
<td></td>
<td>361</td>
</tr>
<tr>
<td>MAN (menthyl anthranilate)</td>
<td>5</td>
<td></td>
<td></td>
<td>363</td>
</tr>
<tr>
<td>TiO&lt;sub&gt;2&lt;/sub&gt; (titanium dioxide)</td>
<td>25</td>
<td></td>
<td></td>
<td>379&lt;sup&gt;4,5&lt;/sup&gt;</td>
</tr>
<tr>
<td>ZnO (zinc oxide)</td>
<td>25</td>
<td></td>
<td></td>
<td>382&lt;sup&gt;4&lt;/sup&gt;</td>
</tr>
<tr>
<td>AVO (avobenzone)</td>
<td>3</td>
<td></td>
<td></td>
<td>383</td>
</tr>
</tbody>
</table>

<sup>1</sup>The maximum concentration established in the Sunscreen Drug Products for Over-the-Counter Human Use; Final Monograph

<sup>2</sup>The UV attenuation is based on substrate spectrophotometry determinations. Filters were prepared in a representative oil in water emulsion.

<sup>3</sup>Determined at 2% o/w emulsion

<sup>4</sup>Determined at 15% o/w emulsion.

<sup>5</sup>Shape of the UV attenuation spectra varies with particle size.

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Diffey et al., 2000
## Sunscreen filter choice – other considerations

<table>
<thead>
<tr>
<th>Peak UV Absorbance</th>
<th>UV Active</th>
<th>Physical Form</th>
<th>Benefits / Advantages</th>
<th>Potential Watch Outs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Avobenzene</td>
<td>oil soluble solid</td>
<td>High extinction</td>
<td>Photostability, solubility</td>
</tr>
<tr>
<td>UVA-I</td>
<td>Zinc Oxide</td>
<td>insoluble solid</td>
<td>Skin protectant (but not claimed in sunscreens)</td>
<td>Basic pH, anionic ingredient compatibility, cannot combine with avobenzone**</td>
</tr>
<tr>
<td></td>
<td>Titanium Dioxide</td>
<td>insoluble solid</td>
<td>High extinction</td>
<td>Whitening (often need to mask with pigments), cannot combine with avobenzone**</td>
</tr>
<tr>
<td></td>
<td>(bigger size)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UVA-II / UVB</td>
<td>Oxybenzone</td>
<td>oil soluble solid</td>
<td>High extinction, boosts SPF</td>
<td>Yellow color, solubility</td>
</tr>
<tr>
<td></td>
<td>Octocrylene</td>
<td>oily liquid</td>
<td>High extinction, photostabilizes avobenzone</td>
<td>Thick / heavy feel</td>
</tr>
<tr>
<td></td>
<td>Meradimate</td>
<td>oily liquid</td>
<td>----</td>
<td>Non-global, limited use*</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UVB</td>
<td>Ensulizole</td>
<td>water soluble solid (when neutralized)</td>
<td>Very high extinction, water soluble (if neutralized)</td>
<td>Water resistance, cannot combine with avobenzone</td>
</tr>
<tr>
<td></td>
<td>Octinoxate</td>
<td>oily liquid</td>
<td>High extinction</td>
<td>Photostability when combined with avobenzone</td>
</tr>
<tr>
<td></td>
<td>Titanium Dioxide</td>
<td>insoluble solid</td>
<td>High extinction</td>
<td>Cannot combine with avobenzone**</td>
</tr>
<tr>
<td></td>
<td>(smaller size)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Octisalate</td>
<td>oily liquid</td>
<td>Low cost</td>
<td>Low extinction</td>
</tr>
<tr>
<td></td>
<td>Homosalate</td>
<td>oily liquid</td>
<td>Low cost</td>
<td>Low extinction</td>
</tr>
<tr>
<td></td>
<td>Octyldimethyl PABA</td>
<td>oily liquid</td>
<td>----</td>
<td>Limited use*</td>
</tr>
</tbody>
</table>

* Almost no use in the market-place today

** Combination not allowed under current FDA Monograph
As a rule of thumb, doubling SPF can almost double sunscreen content.

SPF 15 ≈ 12% sunscreen active
SPF 30 ≈ 20% sunscreen active
SPF 50 ≈ 30% sunscreen active

Theoretical “diminishing return” in absorption of erythemally-effective UVR and...

...steady accumulation of sunscreen content.
But... as SPF doubles, UVR transmitted to the skin is approximately halved
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Increasing SPF and consequent aesthetic challenge
(Example shown, oil-in-water emulsion)
Increasing SPF – the effect on the $$ cost of protection

Example of the effect of increasing SPF on absolute and relative formulation cost (in an oil-in-water emulsion)

<table>
<thead>
<tr>
<th>Product SPF</th>
<th>Formula Cost ($ / kg)</th>
<th>Vehicle* Cost (% of formula)</th>
<th>UV Filter Cost (% of formula)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>$X</td>
<td>53%</td>
<td>47%</td>
</tr>
<tr>
<td>15</td>
<td>$1.3X</td>
<td>42%</td>
<td>58%</td>
</tr>
<tr>
<td>30</td>
<td>$1.7X</td>
<td>31%</td>
<td>69%</td>
</tr>
<tr>
<td>50</td>
<td>$2.3X</td>
<td>24%</td>
<td>76%</td>
</tr>
</tbody>
</table>

*Vehicle = emollients, thickener(s), emulsifier(s), and preservative(s)
UV filters, their effect on perceived skin feel... and, therefore, consumer usage

• Polar oils – “...greasy, heavy...”
• Oil-soluble crystalline solids (need high solvent) – “...greasy...”
• Water-soluble salts (counter thickeners and need more polymer) – “...heavy, greasy...”
• Insoluble particulates – “...draggy, dry...”

And... all the above accentuated by SPF and film thickness.

These attributes are real usage-killers, reflected partly in known low sunscreen usage, low rates of re-application, etc.
UV filters, their effect on perceived skin feel... and, therefore, consumer usage

Overcoming consumer usage issues via efficiency:

- Film-formers, shear-thinning emollients
- Combining oil and water-soluble sunscreens in one formulation
- Using photostable sunscreens
- Using photostable sunscreen combinations

Overcoming consumer usage issues via skin-feel:

- Particulates to reduce greasy skin-feel
- Using oil-soluble, film-forming thickeners to reduce greasy skin-feel
- Using silicone emollients to reduce draggy skin-feel of ZnO, TiO₂
- Using alternative product forms (e.g., rub-free sprays)
Sunscren active choice – photostability

Avobenzone (AVO; butyl methoxydibenzoylmethane)

Well-characterised and understood photochemistry underlying AVO instability.
Sunsreen active choice – photostability

Various formulation strategies can now be deployed to help stabilize Avobenzone:

– Octocrylene
– Polycrylene (Polyester-8)
– Corapan TQ (Diethylhexyl 2,6-Naphthalate)
– Hallbrite BHB (Butyloctyl salicylate)

Note: photostability is taken into account in SPF testing of final formulations.
Vehicle optimization

Choice of vehicle is critical – to drive *efficiency* (extracting maximum efficacy from minimal sunscreen).

Vehicle excipients can significantly enhance the optical performance of a sunscreen system, e.g.,

- Improving solubility and dispersion of solid ingredients
- Optimizing the “spectral shift” of UV filters
- Enhancing internal scatter (and, therefore, optical path length) for increased absorption
Vehicle optimization – UV filter solubility and dispersion

Organic Filters:

• **Solvents**: solid UV filters (e.g., avobenzone, oxybenzone) require solvent oils for maximum efficiency
  – Higher solubility = lower UV filter concentration needed
  – Can be used to “tune” spectral absorption profile to a limited degree

Inorganic Filters:

• **Dispersing oils / dispersing aids**: can optimize particulate dispersion and suspension, when combined with effective mixing

• **Viscosity modifiers**: thixotropic (shear-thinning) materials can further aid particulate suspension and skin distribution

• **Film-forming polymers**: can help “lock” UV filters to the skin surface
Vehicle optimization – choice of solvent

Solvents can optimize UV filter efficacy and efficiency

- Solid UV filters must be completely soluble for optimal efficacy
- Solvent polarity can change spectral absorption maxima and extinction coefficients.

Note: examples show published spectral shifts in pure solvent systems.
Vehicle optimization – other considerations

Sunscreen formulators need technology and skill to overcome other issues with:

Film continuity / uniformity

• Gaps in film have significant impact on efficacy.
• On-skin rheology / tribology critical to spreading and final film formation.

Microbial preservation

• Sunscreen products are notoriously difficult to preserve.
• High levels of polar oil UV filters often cause preservatives to partition out of aqueous phase.
Characterizing spray particle size

Laser diffraction is a widely-used particle-sizing technique for materials ranging from 0.1 micron (100nm) up to several millimeters in size.

- Wide dynamic range – covering 4 orders of magnitude.
- Particle size distribution enables assessment of potential respirable fraction of spray; packaging / formulation can be modified to minimize particles of respirable size.

From Malvern website and J&J submission, 2009
Formulation of Sunscreen Products

Summary

• Technical performance is of primary concern and we formulate to achieve specific UVR attenuation targets (amplitude and breadth).

• We have an effective toolbox of UV filters (the Sunscreen Monograph).

• We also place extremely high importance on formulating for efficiency and optimal consumer usage.

In summary, this means that the formulator is managing and balancing a number of factors, including efficacy / safety, aesthetics, cost, stability and skin compatibility.
Testing of Sunscreen Products

Are SPF values driven by “active” UV filters only or contributions from “inactive” ingredients also?

- *In vivo* SPF testing should not be a blind process – *in vitro* testing can help predict expected performance.
- SPF testing is performed on the whole sunscreen product as marketed.
- SPF values depend on the total formulation and the manufacturing process used to produce it.
Testing of Sunscreen Products

Claims that excipients such as vitamins are used to artificially-inflate SPF values are not evidence-based:

- The Agency has acknowledged that any moderation of erythema by anti-inflammatoryatories is relatively short-lived when compared with the time-frame of erythema measured in *in vivo* SPF testing.

- Controlled *in vivo* SPF testing demonstrating such activity for these excipients is lacking. Some *in vitro* data have reported an impact on SPF, but are not a reliable indicator of *in vivo* SPF performance.

- Recent experimental data¹ have shown no significant difference in MED between an SPF16 sunscreen with or without 0.1% hydrocortisone.

- Market survey data² does not show a clear correlation of higher SPF with inclusion of these excipients.

¹Staton J., Feng H., Asian Societies of Cosmetic Scientists Conference, Cairns, 2015
Testing of Sunscreen Products

Should the SPF test application rate be changed from 2mg/cm² to 1mg/cm²?

- PCPC agrees with the reasoning of FDA in the 2011 Final Labelling Rule:
  - 2mg/cm² is needed for adequate application in the test procedure and for reliable, reproducible results (Bimczok¹).
  - All *in vivo* SPF and UVA test standards (including ISO24444) use a dose of 2mg/cm².

Testing of Sunscreen Products

Should changes be made to the SPF Test Method?

• Modifications to ISO24444 (*In vivo* SPF Method) are expected (2016-2019)
  
  – Based on ongoing research and inter-laboratory testing, modifications may be anticipated to the ISO SPF and Water Resistance SPF Standards.

  – FDA could consider harmonizing on the statistical approach used globally for 10-subject panels (see ISO24444).
Testing of Sunscreen Products

Is a Critical Wavelength (CW) threshold of 370nm adequate to protect against UVA-I?

• We believe that a criteria of CW ≥ 370nm is adequate to ensure that sunscreen products protect against UVA-I (340-400nm).

• By definition, if CW ≥ 370nm (i.e., ≥10% absorbance above 370nm), much higher absorbance must occur 340-370nm).

• A CW ≥ 370nm:
  - Requires the presence of adequate levels of UVA-I filter(s) - avobenzone, ZnO, TiO₂
  - Ensures UVA protection commensurate with SPF.
Skin penetration and safety evaluation

“500 Dalton Rule”

Published data (in vitro, animal in vivo, human clinical), suggests that dermal penetration is low overall for organic filters*.

Penetration is a function of molecular weight (MW), but also partition coefficient, charge density, molecular geometry and other physical / chemical properties.

• In general, penetration declines significantly for materials >500 Daltons MW.
• Materials of similar MW may penetrate to different extents based on other physico-chemical properties.

The systemic exposure of UV filters is accounted for in the quantitative human safety assessment.

* There is no evidence that nano TiO₂ or ZnO penetrate beyond the stratum corneum.
Lack of impact of sunscreen vehicle on skin absorption of 2 UV filters

*Procter & Gamble, unpublished data

**In vitro** skin penetration study evaluated skin absorption of 2 UV filters, $^{14}$C-Octocrylene (5%) and $^3$H-Oxybenzone (3%) from representative types of SPF30 sunscreen products dosed at 2mg/cm$^2$ (24hr data).

Objective was to evaluate variation among typical formulations (not for quantitative assessment).

Each formula contained 3 additional UV filters and excipients typical for the product form. Face product also contained tocopheryl acetate, retinyl palmitate and panthenol.

No significant differences observed in extent of penetration between the vehicle types.
Coatings on nano-materials

TiO$_2$ and ZnO can be treated with surface coatings to help them disperse evenly in product (efficacy), to reduce surface photocatalytic activity and improve aesthetics:

• Typical coatings are cosmetic excipients with established safety profiles (e.g., silicas, silanes, aluminum hydroxide);

• Coatings are treated like other ingredients and evaluated for safety;

• There is evidence\(^1\) that coatings do not affect penetration of nano TiO$_2$ or ZnO;

• Any impact of coatings on product efficacy is evaluated in the finished product SPF testing.

\(^1\)Schilling et al., 2010
Formulation safety assessment

Once safety / suitability of each individual ingredient has been established based on quantitative safety assessment, the overall formulation is assessed:

• Confirms that the product in total has an acceptable profile with respect to consumer tolerance and site-of-contact safety endpoints such as:
  – Contact allergy;
  – Phototoxicity / photoallergy;
  – Skin and eye irritation;
  – Sensory effects

• Takes into consideration the impact of ingredients in combination and overall characteristics of a formula, for example:
  – additive or mitigating effects of multiple ingredients to impact irritancy;
  – impact of viscosity on application, or rinsing from the eye, etc.
Post-market surveillance and analysis

Ensures Adverse Events (AEs) are evaluated and managed in a timely manner in order to detect safety signals and inform as to the need for regulatory reporting, change to formulations, labelling, or other market action.

- includes collection of all AEs reported from a variety of sources (consumer, medical professional, regulatory body, etc.)

- appropriate signal detection, analysis and management aids in understanding whether consumer experience is consistent with expected profile based on technical understanding of the formulation and / or pre-market testing, or if unexpected symptoms are being reported.
Concluding Comments

• Sunscreen product manufacturers need to balance multiple, diverse considerations in the formulation and development of efficacious, stable and aesthetically-pleasing products to meet consumer needs.

• The efficacy and safety of sunscreen products marketed under the OTC Monograph is substantiated by assessment of individual ingredients and appropriate testing of the finished product in total.

• These evaluations confirm that a variety of formulations perform as expected, providing safe and effective sunscreen protection to our consumers.
This presentation was sourced from published, peer-reviewed literature (cited and below) and manufacturer data on file

How sunscreens work


The safety evaluation of UV filters


The safety evaluation of UV filters (cont.)


Risk of UVR exposure and benefits of sunscreen use


Risk of UVR exposure and benefits of sunscreen use (cont.)


Sunscreen use in the US population


Department of Dermatology and Cutaneous Surgery, University of Miami Miller School of Medicine, Journal of Skin Cancer. Volume 2014, Article ID 285357


Sunscreen use in the US population (cont.)


IRI Info Scan, data on file


Sunscreen use in the US population (cont.)
