Personal Care Products Council
Committed to Safety, Quality & Innovation

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PCPC Additional Comments on FDA's Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry (FDA-2023-D-1716)

On behalf of the Personal Care Products Council (PCPC), I am pleased to submit the following comments in response to FDA's "Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry" published in the Federal Register on August 8, 2023, under Docket No. FDA-2023-D-1716 (the "draft guidance"), "Structured Product Labeling (SPL) Implementation Guide with Validation Procedures" (the "SPL Guide") published in a Constituent Update on October 13, 2023 (updated November 14, 2023), "FDA Issues Compliance Policy for Cosmetic Product Facility Registration and Cosmetic Product Listing" (the "compliance policy") published in a Constituent Update on November 8, 2023, and "Compliance Policy for Cosmetic Product Facility Registration and Cosmetic Product Listing; Guidance for Industry; Availability" published in the Federal Register on November 9, 2023, under Docket No. FDA-2023-D-1716 (the "compliance policy").

PCPC previously submitted comments in response to the draft guidance on September 7, 2023, and initial observations on the SPL Guide on October 18, 2023. PCPC has also submitted comments in response to FDA's other recent consultations on the cosmetic registration and listing activities: draft Paperwork Reduction Act (PRA) (FDA-2023-N-1029), pilot program (FDA-2023-N-3107), and final PRA, draft registration and listing forms, and draft screenshots (FDA-2023-N- 1029). This submission supplements PCPC's previous comments.

PCPC appreciates FDA's work to effectively implement the Modernization of Cosmetics Regulation Act (MoCRA) of 2022. Strongly supported by PCPC and our member companies, this historic legislation provided FDA with additional, meaningful tools to ensure cosmetic safety and to protect public health, reinforcing consumer confidence in the products trusted and used every day. We look forward to continuing to provide input to FDA as the Agency works toward successful implementation of the new authorities.

In this letter, we respond to express our support for FDA's compliance policy announcement on enforcement discretion, offer additional feedback on the product categories, request clarification on facilities that must be registered and products that must be listed during the initial period, and offer additional feedback on the SPL Guide, including the recent updates.

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Enforcement Discretion

PCPC supports FDA's compliance policy announcement that the Agency intends to exercise enforcement discretion on the MoCRA facility registration and product listing compliance deadline for six months – moving the compliance date from Dec. 29, 2023, to July 1, 2024. We have provided and are continuing in this letter to offer feedback to FDA on the development of an efficient electronic submission program (Cosmetics Direct). We appreciate FDA's ongoing efforts to develop Cosmetics Direct, paper forms, and technical assistance documents.

In the meantime, PCPC is encouraging our members and the global industry to prepare for all aspects of registration and listing. As part of our outreach efforts, we have shared FDA's instructions for obtaining a Facility Establishment Identifier (FEI) number, and the draft guidance, forms, screenshots, and SPL Guide.

PCPC looks forward to the FDA's public launch of Cosmetics Direct once the platform is complete.

Product Categories

New Basis for Updating List Before the Public Launch

PCPC previously requested in our initial draft guidance and final PRA comments that FDA re-adopt the VCRP product categories through at least the initial cosmetic facility registration and product listing period. We felt that this would be necessary, because of the limited time that

would have been available for companies to update their internal product management databases with the new product categories and to submit all listings between the publication date of the final guidance and the statutory date of December 29, 2023. However, the amount of time available for companies to update their internal product management databases with the new product categories will likely now no longer be as limited following FDA's compliance policy of a July 1, 2024, deadline, assuming the final guidance is published in December 2023 as anticipated by the Agency.

We are updating our previous request to ask that FDA adopt any necessary changes to the VCRP product categories before the public launch of Cosmetics Direct. We now believe that it would be much more challenging for companies to enter the original VCRP product categories in their submissions through July 1, 2024, and update these submissions with any changes made by FDA to the product categories, as necessary, at the time of renewal. Any changes to the product categories between the initial period and first renewal period would likely result in a substantial number of listings that would need to be submitted outside of FDA's "abbreviated renewal" process, which we expect would be unnecessarily burdensome for both any impacted companies and FDA staff. Also, all such listings would need to be updated (to discontinue) and re-submitted with the updated category if FDA does not allow updates to product categories as proposed in the updated SPL Guide (discussed further in the "SPL Guide" section in this letter).

Background on the Development of This Additional Feedback

In our previous comments, we noted our intention to share additional feedback on the product categories with FDA. This delay was necessary due to our focus on providing feedback to FDA on other important topics in the draft guidance, final PRA, etc. and based on the need for PCPC to solicit additional feedback from our member companies and other stakeholders. In particular, we used this time to discuss potential additional feedback on the product categories with Dr. Bart Heldreth, Executive Director, the Cosmetic Ingredient Review (CIR).

Our additional feedback on the product categories is intended to address what we understand are FDA's regulatory needs, to support the Expert Panel's safety assessments of cosmetic ingredients, and to help limit the complexity of the list so that companies would be able to readily select any product category applicable to their cosmetic products listed with FDA.

Additional Feedback and Proposal for Certain Exposure Categories

PCPC is proposing two scenarios that we expect will address the needs of all stakeholders in Appendix A of this letter. We strongly prefer and recommend that FDA adopt Scenario #1. In Scenario #1, PCPC is proposing that FDA add new exposure categories on "Baby or child intended use" and "Sprays and powders," and the specified subcategories. We expect that these new exposure categories would have a significant benefit for safety assessments of cosmetic ingredients.

FDA and CIR have both proposed subcategories to collect this exposure information for a subset of the product categories. However, we are concerned that some of those proposed subcategories would add to the complexity of the list and make it more difficult for companies to select a product category. Both FDA and CIR proposals would also only capture this exposure information for a subset of the product categories. We believe that FDA could collect more of this important exposure information under Scenario #1, than would be possible in both FDA and CIR's proposals, while also limiting the burden on industry.

If FDA adopts the exposure categories proposed by PCPC in our Scenario #1, then we request that FDA also include instructions for companies to select a traditional category, e.g., "Shampoos," "Foundations," "Disposable wipes," etc., in addition to any exposure category that may be selected. This would be enabled by FDA's confirmation that it will accept the entry of one or more product categories on each cosmetic product listing as authorized under MoCRA. We also request that FDA issue an ingredient frequency of use by product category report to support both FDA's regulatory needs and the Expert Panel's safety assessments of cosmetic ingredients. We understand that CIR intends to request this information via FOIA from FDA, to support the Expert Panel, as was their practice with the VCRP. It will be important that such an FDA report include information on combinations of product categories associated with each ingredient use, so that all ingredient uses are correctly counted once even if the same use was listed in multiple product categories. If our requests in this section cannot be addressed, only then would we recommend Scenario #2 to FDA.

We request that FDA adopt the product categories proposed in Appendix A of this letter. Our feedback on the product categories is structured as a table and includes a comparison of the product categories from the VCRP, what was proposed by FDA in the draft guidance, PCPC's preferred Scenario #1 with exposure categories, and PCPC's back-up Scenario #2 that we only recommend if instructions and frequency of use reports cannot be developed for Scenario #1. PCPC has also included comments in Appendix A to support various proposed changes.[1]

Request for Product Categories to be Entered on Listing Only

We repeat our request from our previous letters that FDA not require the re-entry of the product categories on the final registration form, because this information would be submitted to the Agency on the final listing form under the same FEI number. PCPC has proposed updating the product categories to support the needs of FDA, the Expert Panel, and industry for cosmetic product listings. If FDA were to require the re-entry of this expanded list of product categories for facility registrations, then responsible persons would need to collaborate on the list of product categories with their contract manufacturers to ensure that the product categories on both forms associated with each FEI number exactly match. (The same issue exists with the other proposed facility registration fields associated with an FEI number on product listing form: brand names and responsible person names.) This would also be an unnecessarily duplicative requirement that

[1] Please note that PCPC is not providing feedback on FDA's proposed "Tattoo preparations" categories.

would not result in FDA receiving any additional information that would be useful for the Agency's purposes.

Initial Registration and Listing

We request that FDA clarify that contract facilities that will have stopped manufacturing or processing cosmetic products by July 1, 2024, do not need to be registered. PCPC's members want to ensure compliance with all MoCRA requirements, including the registration of their facilities, however, there is a concern that it may be difficult to persuade a former contractor to register a facility for cosmetic activities in which they are no longer engaged. While MoCRA authorizes responsible persons to register their contract manufacturer's facilities, we understand that at least some of PCPC's members have determined that they cannot take responsibility for registering a facility with which they no longer have a contractual relationship.

Furthermore, we are concerned that responsible persons whose cosmetic products were previously manufactured or processed at such facilities may not be able to complete their listings if the facility has stopped manufacturing or processing those cosmetic products by July 1, 2024, and, for the reasons discussed in the above paragraph, may not be registered with FDA. FDA's draft listing form proposed to require the entry of the FEI number of all facilities, which must also be registered for their cosmetic activities, except in the case of a facility that will be an exempt small business. Without a similar exception for facilities that will no longer be manufacturing or processing cosmetic products, it will not be possible for responsible persons to complete their listings in these cases. To address these concerns, we repeat our request from our final PRA comments:

> We request that FDA modify for the final listing form the field "FDA ESTABLISHMENT IDENTIFIER…(if the facility is as small business and is not required to register, please enter the name and address of the facility)*" to "…(if the establishment is not required to register, e.g., small business, etc., please enter the name and address of the establishment)*".

Similarly, we request that FDA clarify that cosmetic products that the responsible person has not directly placed into interstate commerce on or after December 29, 2022, do not need to be listed. PCPC's members want to ensure compliance with all MoCRA requirements, including the listing of their cosmetic products, however there is a concern that it may be difficult to determine what cosmetic products were still offered for sale in the U.S. on or after December 29, 2022, if the responsible person stopped directly marketing such products before this date. We ask that FDA consider that not every company has access to the type of information that could help inform their understanding of when a cosmetic product was potentially marketed by a third party. We are concerned that a retailer, etc. may not inform the responsible person that a cosmetic product, discontinued by the responsible person before December 29, 2022, was at any time marketed after this date. If FDA were to expect the listing of such products, then a responsible person may feel obligated to list cosmetic products that they discontinued potentially years before MoCRA.

This would significantly increase the number of cosmetic products that should be listed with FDA, which would also be unnecessarily burdensome. We presume that FDA will have a much greater interest in cosmetic products that have not been discontinued, and these should be prioritized.

FEI Question on Listing Form

In our comments on the final PRA and draft forms, we requested that FDA modify for the final listing form the field "FDA ESTABLISHMENT IDENTIFIER…(if the facility is as small business and is not required to register, please enter the name and address of the facility)*" to "…(if the establishment is not required to register, e.g., small business, etc., please enter the name and address of the establishment)*". We are expanding upon that comment with a request that FDA modify for Cosmetics Direct the field "IS THIS A SMALL BUSINESS?*" to "DOES THIS FACILITY HAVE AN FEI NUMBER?*" This clarification is necessary, because the responsible person may not know whether their contract manufacturer is a small business. Contract manufacturers would not be obligated by the FD&C Act to share such information with their clients. Furthermore, we understand that at least some PCPC members who are preparing to list cosmetic products with FDA have been unable to confirm whether their contract manufacturers are small businesses. We believe it would be reasonable for FDA to ask if a facility has an FEI number, as opposed to the proposed small business question, because responsible persons may look up the FEI number using FDA's FEI Search Portal.

SPL Guide

Following our review of the SPL Guide, PCPC would like to emphasize our request that FDA offer ample and early training opportunities for all interested stakeholders who intend to register or list their cosmetic activities through July 1, 2024. We understand there are many such companies that have no experience with FDA's SPL process, in particular small-to-medium sized businesses and foreign companies that do not market drugs or devices in the U.S. While the SPL Guide will be critical to help many of these companies learn how to create an SPL-formatted submission, we have heard that the length and complexity of the document will necessitate some official training to help companies get started. We also understand that there is a demand for training specific to the new cosmetic forms from companies that have previously created SPL-formatted drug or device submissions. We request that FDA offer training on SPL-formatted submissions (e.g., SPL Guide, bulk submissions, etc.), Cosmetics Direct, Electronic Submissions Gateway (ESG), and Xforms.

We request that FDA modify the SPL Guide so that companies can submit their product listings without any validation based on what another company has or has not submitted to FDA. We are concerned by FDA's proposed validation in section 36.1.6.5, "Facility Product Link" (product listing), of the updated SPL Guide: "If there is no SPLSMALLBUSINESS designation, then there is an active facility registration for this facility and their respective "responsible person" as the labeler of this file." We believe this draft validation means that companies will only be able

to list a cosmetic product if the responsible person name will be entered on the listing form exactly as it was entered on the registration form, and that such a registration must have been previously submitted and included the responsible person name.

If our understanding is correct, then responsible persons would be unable to submit their listings in the case of a misspelling of their name (or minor variation, such as "Incorporated" vs. "Inc.") entered by another party on the registration form. Such a facility registration may also be submitted by a competitor of the responsible person who contracts with the same facility and may not have entered the responsible person name on the registration. The facility registration may also be submitted right before FDA's updated compliance deadline, July 1, 2024, which would leave very little, if any, time for the responsible person to submit their product listings. None of these errors would be the fault of the responsible person, however they could result in major delays in the submission of product listings while the responsible person waits for another party to submit or make the necessary modifications to the facility registration. If those efforts are not successful, we expect the responsible person will need to submit a new, possibly duplicate, facility registration with the correct information.

We appreciate that FDA has removed from section 36.1.6.5 of the updated the SPL Guide the previously proposed validation on "same product brand name." We believe that such a requirement would have had similar issues as identified in the above paragraphs and would have potentially resulted in many more errors due to the large number of product brand names.

We request that FDA modify the SPL Guide so that companies can update any required field on their previously submitted product listings. We are concerned by FDA's proposed validation in section 36.2.2.8 and 36.2.2.9, part of "Cosmetic Product" (product listing), of the updated SPL Guide: "Name, ingredients (including fragrance, color, and flavor) match the name for the cosmetic product, as such name appears on the label previously assigned to this listing number and the responsible person's name included in the previous version of this file" and "Cosmetic types matches the cosmetic product category previously assigned to this listing number." We believe that this draft validation means that responsible persons will not be able to update their product listings, even though this is required by Section 607(c)(5) of the FD&C Act, in the case of any changes to the product name, ingredients, responsible person, or product categories.

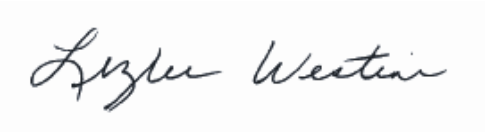
We understand that updates to the information in these fields will be common, especially for ingredients. If these errors were to occur, responsible persons will need to update (to discontinue) all such product listings and submit new product listings with the updated information. Any requirement to both update (to discontinue) and submit a new listing would take 1.25 hours on average, compared to just 0.25 hours for an update, according to FDA's estimates in the final PRA. We are not aware of any reasonable justification for restricting which fields can be updated and thus the proposed validation appears to be unnecessarily burdensome.

PCPC is still reviewing the SPL Guide and we may submit additional feedback to FDA on this important document.

Conclusion

Thank you for considering these comments on FDA's draft guidance, SPL Guide, and compliance policy. We hope this feedback is helpful in understanding PCPC members' perspectives and would be pleased to respond to any questions or requests for further information. We welcome any opportunity to meet with FDA staff to discuss the recommendations in this letter.

Sincerely



Lezlee Westine
President & CEO

Personal Care Products Council
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Appendix A – Cosmetic Product Categories

VCRP Categories 3.26.23	**FDA Draft Guidance 8.7.23**	**PCPC Proposal w/ Exposure Categories (Scenario #1)**	**PCPC Proposal w/o Exposure Categories (Scenario #2)**	**PCPC Comments**
		(00) Baby or child intended use (if applicable).		
		(a) Babies (0-12 months).		PCPC agrees with CIR's suggestions. We are proposing age ranges for these subcategories that align with 21 CFR 105.3(e) of FDA's food regulations.
		(b) Children (1-12 years).		
		(01) Sprays and powders (if applicable).		
		(a) Pump spray.		PCPC agrees with CIR's suggestions.
		(b) Propellant spray.		
		(c) Propellant foam.		
		(d) Airbrush delivery system.		
		(e) Pressed powder.		
		(f) Loose powder.		
(1) ***Baby products.***	(01) ***Baby products.***		(01) ***Baby products.***	Not necessary in scenario #1.
(i) Baby shampoos.	(a) Baby shampoos.		(a) Baby shampoos.	
(ii) Lotions, oils, powders, and creams.	(b) Lotions, oils, powders, and creams.		(b) Lotions, oils, powders, and creams.	
	(c) Baby wipes.		(c) Baby wipes.	

VCRP Categories 3.26.23	**FDA Draft Guidance 8.7.23**	**PCPC Proposal w/ Exposure Categories (Scenario #1)**	**PCPC Proposal w/o Exposure Categories (Scenario #2)**	**PCPC Comments**
(iii) Other baby products.	(d) Other baby products.		(d) Other baby products.	
	1. Leave-on.		1. Leave-on.	
	2. Rinse-off.		2. Rinse-off.	
(2) ***Bath preparations.***	(02) ***Bath preparations.***	(02) ***Bath preparations (diluted before use).***	(02) ***Bath preparations (diluted before use).***	PCPC proposes FDA add "diluted before use."
(i) Bath oils, tablets, and salts.	(a) Bath oils, tablets, and salts.	(a) Bath oils, tablets, and salts.	(a) Bath oils, tablets, and salts.	
(ii) Bubble baths.	(b) Bubble baths.	(b) Bubble baths.	(b) Bubble baths.	
(iii) Bath capsules.	(c) Bath capsules.	(c) Bath capsules.	(c) Bath capsules.	
(iv) Other bath preparations.	(d) Other bath preparations.	(d) Other bath preparations.	(d) Other bath preparations.	
(3) ***Eye makeup preparations.***	(03) ***Eye makeup preparations (other than children's eye makeup preparations).***	(03) ***Eye makeup preparations.***	(03) ***Eye makeup preparations (other than children's eye makeup preparations).***	
(i) Eyebrow pencil.	(a) Eyebrow pencils.	(a) Eyebrow pencils.	(a) Eyebrow pencils.	
(ii) Eyeliner.	(b) Eyeliners.	(b) Eyeliners.	(b) Eyeliners.	
(iii) Eye shadow.	(c) Eye shadows.	(c) Eye shadows.	(c) Eye shadows.	
(iv) Eye lotion.	(d) Eye lotions.	(d) Eye lotions.	(d) Eye lotions.	

VCRP Categories 3.26.23	**FDA Draft Guidance 8.7.23**	**PCPC Proposal w/ Exposure Categories (Scenario #1)**	**PCPC Proposal w/o Exposure Categories (Scenario #2)**	**PCPC Comments**
(v) Eye makeup remover.	(e) Eye makeup removers.	(e) Eye makeup removers.	(e) Eye makeup removers.	
	(f) False eyelashes.	(f) False eyelashes.	(f) False eyelashes.	
(vi) Mascara.	(g) Mascaras.	(g) Mascaras.	(g) Mascaras.	
	(h) Eyelash and eyebrow adhesives, glues, and sealants.	(h) Eyelash and eyebrow adhesives, glues, and sealants.	(h) Eyelash and eyebrow adhesives, glues, and sealants.	
	(i) Eyelash and eyebrow preparations (primers, conditioners, serums, fortifiers).	(i) Eyelash and eyebrow preparations (primers, conditioners, serums, fortifiers).	(i) Eyelash and eyebrow preparations (primers, conditioners, serums, fortifiers).	
	(j) Eyelash cleansers.	(j) Eyelash cleansers.	(j) Eyelash cleansers.	
(vii) Other eye makeup preparations.	(k) Other eye makeup preparations.	(k) Other eye makeup preparations.	(k) Other eye makeup preparations.	
	(04) ***Children's eye makeup preparations.***		(04) ***Children's eye makeup preparations.***	Not necessary in scenario #1.
	(a) Children's eyeshadows.		(a) Children's eyeshadows.	

VCRP Categories 3.26.23	**FDA Draft Guidance 8.7.23**	**PCPC Proposal w/ Exposure Categories (Scenario #1)**	**PCPC Proposal w/o Exposure Categories (Scenario #2)**	**PCPC Comments**
	(b) Other children's eye makeup.		(b) Other children's eye makeup.	
(4) ***Fragrance preparations.***	(05) ***Fragrance preparations.***	(04) ***Fragrance preparations.***	(05) ***Fragrance preparations.***	
(i) Colognes and toilet waters.	(a) Colognes and toilet waters.	(a) Perfumes, colognes, and toilet waters.	(a) Perfumes, colognes, and toilet waters.	The terms perfumes, colognes, etc. differ only in a marketing context. PCPC recommends FDA combine these categories.
(ii) Perfumes.	(b) Perfumes.			
(iii) Powders (dusting and talcum) (excluding aftershave talc).	(c) Powders (dusting and talcum) (excluding aftershave talc).	(b) Powders (dusting and talcum) (excluding aftershave talc).	(b) Powders (dusting and talcum) (excluding aftershave talc).	
(iv) Sachets.				PCPC supports FDA proposal.
(v) Other fragrance preparations.	(d) Other fragrance preparations.	(c) Other fragrance preparations.	(c) Other fragrance preparations.	
(5) ***Hair preparations (noncoloring).***	(06) ***Hair preparations (non-coloring).***	(05) ***Hair preparations (non-coloring).***	(06) ***Hair preparations (non-coloring).***	
(i) Hair conditioners.	(a) Hair conditioners.	(a) Hair conditioners.	(a) Hair conditioners.	
	1. Leave-on.	1. Leave-on.	1. Leave-on.	
	2. Rinse-off.	2. Rinse-off.	2. Rinse-off.	

VCRP Categories 3.26.23	**FDA Draft Guidance 8.7.23**	**PCPC Proposal w/ Exposure Categories (Scenario #1)**	**PCPC Proposal w/o Exposure Categories (Scenario #2)**	**PCPC Comments**
(ii) Hair sprays (aerosol fixatives).	(b) Hair sprays (aerosol fixatives).	(b) Hair sprays.	(b) Hair sprays (aerosol fixatives).	
(iii) Hair straighteners.	(c) Hair straighteners.	(c) Hair straighteners.	(c) Hair straighteners.	
(iv) Permanent waves.	(d) Permanent waves.	(d) Permanent waves.	(d) Permanent waves.	
(v) Rinses (noncoloring).	(e) Rinses (non-coloring).	(e) Rinses (non-coloring).	(e) Rinses (non-coloring).	
(vi) Shampoos (noncoloring).	(f) Shampoos (non-coloring).	(f) Shampoos (non-coloring).	(f) Shampoos (non-coloring).	
	1. Leave-on.			Except for dry shampoos (which we are proposing FDA add), all shampoos are rinse-off.
	2. Rinse-off.			
		(g) Dry shampoos (non-coloring)	(g) Dry shampoos (non-coloring)	PCPC agrees with CIR's suggestion.
(vii) Tonics, dressings, and other hair grooming aids.	(g) Tonics, dressings, and other hair grooming aids.	(g) Tonics, dressings, and other hair grooming aids.	(g) Tonics, dressings, and other hair grooming aids.	
(viii) Wave sets.	(h) Wave sets.	(h) Wave sets.	(h) Wave sets.	
(ix) Other hair preparations.	(i) Other hair preparations.	(i) Other hair preparations.	(i) Other hair preparations.	
	1. Leave-on.	1. Leave-on.	1. Leave-on.	
	2. Rinse-off.	2. Rinse-off.	2. Rinse-off.	

VCRP Categories 3.26.23	**FDA Draft Guidance 8.7.23**	**PCPC Proposal w/ Exposure Categories (Scenario #1)**	**PCPC Proposal w/o Exposure Categories (Scenario #2)**	**PCPC Comments**
(6) ***Hair coloring preparations.***	(07) ***Hair coloring preparations.***	(06) ***Hair coloring preparations.***	(07) ***Hair coloring preparations.***	
(i) Hair dyes and colors (all types requiring caution statement and patch test).	(a) Hair dyes and colors (all types requiring caution statement and patch test).	(a) Permanent hair dyes and colors (all types requiring caution statement and patch test).	(a) Permanent hair dyes and colors (all types requiring caution statement and patch test).	Many of these hair color categories can be combined as they represent similar chemistries and exposures. In their place, PCPC is proposing separate categories for permanent and temporary.
		(b) Temporary hair dyes and colors	(b) Temporary hair dyes and colors	PCPC agrees with CIR's suggestion.
(ii) Hair tints.	(b) Hair tints.			PCPC proposes incorporating these categories above.
(iii) Hair rinses (coloring).	(c) Hair rinses (coloring).			
	1. Leave-on.			
	2. Rinse-off.			
(iv) Hair shampoos (coloring).	(d) Hair shampoos (coloring).			
	1. Leave-on.			
	2. Rinse-off.			
(v) Hair color sprays (aerosol).	(e) Hair color sprays (aerosol).		(c) Hair color sprays (aerosol).	Not necessary in scenario #1.

VCRP Categories 3.26.23	**FDA Draft Guidance 8.7.23**	**PCPC Proposal w/ Exposure Categories (Scenario #1)**	**PCPC Proposal w/o Exposure Categories (Scenario #2)**	**PCPC Comments**
(vi) Hair lighteners with color.	(f) Hair lighteners with color.	(c) Hair lighteners with color.	(d) Hair lighteners with color.	
(vii) Hair bleaches.	(g) Hair bleaches.	(d) Hair bleaches.	(e) Hair bleaches.	
	(h) Eyelash and eyebrow dyes.	(e) Eyelash and eyebrow dyes.	(f) Eyelash and eyebrow dyes.	
		(f) Hair dye removal	(g) Hair dye removal	PCPC proposes FDA add.
(viii) Other hair coloring preparations.	(i) Other hair coloring preparations.	(g) Other hair coloring preparations.	(h) Other hair coloring preparations.	
	1. Leave-on.	1. Leave-on.	1. Leave-on.	
	2. Rinse-off.	2. Rinse-off.	2. Rinse-off.	
(7) ***Makeup preparations (not eye).***	(08) ***Makeup preparations (not eye)(other than makeup preparations for children).***	(07) ***Makeup preparations (not eye).***	(08) ***Makeup preparations (not eye)(other than makeup preparations for children).***	
(i) Blushers (all types).	(a) Blushers and rouges (all types).	(a) Blush and cheek color (all types).	(a) Blush and cheek color (all types).	PCPC proposes FDA update category name with modern terms.
(ii) Face powders.	(b) Face powders.	(b) Face powders.	(b) Face powders.	
(iii) Foundations.	(c) Foundations.	(c) Foundations.	(c) Foundations.	

VCRP Categories 3.26.23	**FDA Draft Guidance 8.7.23**	**PCPC Proposal w/ Exposure Categories (Scenario #1)**	**PCPC Proposal w/o Exposure Categories (Scenario #2)**	**PCPC Comments**
	1. Traditional applications.		1. Traditional applications.	Not necessary in scenario #1.
	2. Airbrush applications.		2. Airbrush applications.	
(iv) Leg and body paints.	(d) Leg and body paints.	(d) Leg and body paints.	(d) Leg and body paints.	
	1. Traditional applications.		1. Traditional applications.	Not necessary in scenario #1.
	2. Airbrush applications.		2. Airbrush applications.	
(v) Lipstick.	(e) Lipsticks and lip glosses.	(e) Lipsticks and lip glosses.	(e) Lipsticks and lip glosses.	
(vi) Makeup bases.	(f) Makeup bases.	(f) Makeup bases.	(f) Makeup bases.	
	1. Traditional applications.		1. Traditional applications.	Not necessary in scenario #1.
	2. Airbrush applications.		2. Airbrush applications.	
(vii) Rouges.				PCPC supports FDA's proposal.
(viii) Makeup fixatives.	(g) Makeup fixatives.	(g) Makeup fixatives.	(g) Makeup fixatives.	
(ix) Other makeup preparations.	(h) Other makeup preparations.	(h) Other makeup preparations.	(h) Other makeup preparations.	

VCRP Categories 3.26.23	**FDA Draft Guidance 8.7.23**	**PCPC Proposal w/ Exposure Categories (Scenario #1)**	**PCPC Proposal w/o Exposure Categories (Scenario #2)**	**PCPC Comments**
	1. Traditional applications.		1. Traditional applications.	Not necessary in scenario #1.
	2. Airbrush applications.		2. Airbrush applications.	
	(09) ***Makeup preparations for children (not eye).***		(09) ***Makeup preparations for children (not eye).***	Not necessary in scenario #1.
	(a) Children's blushers and rouges (all types).		(a) Children's blush and cheek color (all types).	
	(b) Children's face paints.		(b) Children's face paints.	
	(c) Children's face powders.		(c) Children's face powders.	
	(d) Children's foundations.		(d) Children's foundations.	
	(e) Children's lipsticks and lip glosses.		(e) Children's lipsticks and lip glosses.	
	(f) Children's color hairsprays.		(f) Children's color hairsprays.	
	(g) Other children's makeup.		(g) Other children's makeup.	

VCRP Categories 3.26.23	**FDA Draft Guidance 8.7.23**	**PCPC Proposal w/ Exposure Categories (Scenario #1)**	**PCPC Proposal w/o Exposure Categories (Scenario #2)**	**PCPC Comments**
			1. Traditional applications.	Not necessary in scenario #1. PCPC agrees with CIR's suggestion for scenario #2.
			2. Airbrush applications.	
(8) ***Manicuring preparations.***	(10) ***Manicuring preparations.***	(08) ***Manicuring preparations.***	(10) ***Manicuring preparations.***	
(i) Basecoats and undercoats.	(a) Basecoats and undercoats.	(a) Basecoats and undercoats.	(a) Basecoats and undercoats.	
(ii) Cuticle softeners.	(b) Cuticle softeners.	(b) Cuticle softeners.	(b) Cuticle softeners.	
(iii) Nail creams and lotions.	(c) Nail creams and lotions.	(c) Nail creams and lotions.	(c) Nail creams and lotions.	
(iv) Nail extenders.	(d) Nail extenders.	(d) Nail extenders.	(d) Nail extenders.	
(v) Nail polish and enamel.	(e) Nail polishes and enamels.	(e) Nail polishes and enamels.	(e) Nail polishes and enamels.	
		(f) Nail gels (light activated).	(f) Nail gels (light activated).	PCPC agrees with CIR's suggestion.
(vi) Nail polish and enamel removers.	(f) Nail polish and enamel removers.	(g) Nail polish and enamel removers.	(g) Nail polish and enamel removers.	
(vii) Other manicuring preparations.	(g) Other manicuring preparations.	(h) Other manicuring preparations.	(h) Other manicuring preparations.	

VCRP Categories 3.26.23	**FDA Draft Guidance 8.7.23**	**PCPC Proposal w/ Exposure Categories (Scenario #1)**	**PCPC Proposal w/o Exposure Categories (Scenario #2)**	**PCPC Comments**
		1. Leave-on.	1. Leave-on.	PCPC suggests FDA add.
		2. Rinse-off.	2. Rinse-off.	
(9) ***Oral hygiene products.***	(11) ***Oral products.***	(09) ***Oral products.***	(11) ***Oral care products.***	
(i) Dentifrices (aerosol, liquid, pastes, and powders).	(a) Dentifrices (aerosols, liquids, pastes, and powders).	(a) Dentifrices (aerosols, liquids, pastes, and powders).	(a) Dentifrices (aerosols, liquids, pastes, and powders).	
(ii) Mouthwashes and breath fresheners (liquids and sprays).	(b) Mouthwashes and breath fresheners (liquids and sprays).	(b) Mouthwashes and breath fresheners (liquids and sprays).	(b) Mouthwashes and breath fresheners (liquids and sprays).	
			1. Liquids.	PCPC agrees with CIR's suggestion for scenario #2.
			2. Sprays.	
(iii) Other oral hygiene products.	(c) Other oral products.	(c) Other oral products.	(c) Other oral products.	
(10) ***Personal cleanliness.***	(12) ***Personal cleanliness.***	(10) ***Personal cleanliness.***	(10) ***Personal cleanliness.***	

VCRP Categories 3.26.23	**FDA Draft Guidance 8.7.23**	**PCPC Proposal w/ Exposure Categories (Scenario #1)**	**PCPC Proposal w/o Exposure Categories (Scenario #2)**	**PCPC Comments**
(i) Bath soaps and detergents.	(a) Bath soaps and body washes.	(a) Bath soaps and body washes.	(a) Bath soaps and body washes.	
(ii) Deodorants (underarm).	(b) Deodorants (underarm).	(b) Deodorants (underarm).	(b) Deodorants (underarm).	
	1. Sticks, roll-ons, gels, creams, and wipes.		1. Sticks, roll-ons, gels, creams, and wipes.	Not necessary in scenario #1.
	2. Sprays.		2. Propellent sprays.	Not necessary in scenario #1. PCPC agrees with CIR's suggestion for scenario #2.
			3. Pump sprays.	
		(c) Hand soaps and washes.	(c) Hand soaps and washes.	PCPC recommends that FDA add.
(iii) Douches.	(c) Douches.	(d) Vaginal douches.	(d) Vaginal douches.	PCPC agrees with CIR's suggestion.
(iv) Feminine hygiene deodorants.	(d) Feminine deodorants.	(e) Feminine deodorants.	(e) Feminine deodorants.	
	1. Leave-on.	1. Leave-on.	1. Leave-on.	
	2. Rinse-off.	2. Rinse-off.	2. Rinse-off.	
	(e) Disposable wipes.	(f) Disposable body and baby wipes.	(f) Disposable body wipes.	"Disposable wipes" is too broad for exposure assessments and could be duplicative of other proposed categories (e.g., deodorant, feminine, makeup, etc.) PCPC is suggesting that baby wipes be listed here in Scenario #1 with "Baby" also selected.
		(g) Feminine wipes.	(g) Feminine wipes.	PCPC agrees with CIR's suggestion.

VCRP Categories 3.26.23	**FDA Draft Guidance 8.7.23**	**PCPC Proposal w/ Exposure Categories (Scenario #1)**	**PCPC Proposal w/o Exposure Categories (Scenario #2)**	**PCPC Comments**
(v) Other personal cleanliness products.	(f) Other personal cleanliness products.	(h) Other personal cleanliness products.	(h) Other personal cleanliness products.	
	1. Leave-on.	1. Leave-on.	1. Leave-on.	
	2. Rinse-off.	2. Rinse-off.	2. Rinse-off.	
(11) ***Shaving preparations.***	(13) ***Shaving preparations.***	(11) ***Shaving preparations.***	(13) ***Shaving preparations.***	
(i) Aftershave lotions.	(a) Aftershave lotions.	(a) Aftershave lotions.	(a) Aftershave lotions.	
(ii) Beard softeners.	(b) Beard softeners.	(b) Beard softeners.	(b) Beard softeners.	
(iii) Men's talcum.	(c) Men's talcum.	(c) Men's talcum.	(c) Men's talcum.	
(iv) Preshave lotions (all types).	(d) Pre-shave lotions (all types).	(d) Pre-shave lotions (all types).	(d) Pre-shave lotions (all types).	
(v) Shaving cream (aerosol, brushless, and lather).	(e) Shaving creams (aerosol, brushless, and lather).	(e) Shaving creams and gels (aerosol, brushless, and lather).	(e) Shaving creams and gels (aerosol, brushless, and lather).	PCPC proposes FDA add "gels."
(vi) Shaving soap (cakes, sticks, etc.).	(f) Shaving soaps (cakes, sticks, etc.).	(f) Shaving soaps (cakes, sticks, etc.).	(f) Shaving soaps (cakes, sticks, etc.).	
(vii) Other shaving preparation products.	(g) Other shaving preparation products.	(g) Other shaving preparation products.	(g) Other shaving preparation products.	

VCRP Categories 3.26.23	**FDA Draft Guidance 8.7.23**	**PCPC Proposal w/ Exposure Categories (Scenario #1)**	**PCPC Proposal w/o Exposure Categories (Scenario #2)**	**PCPC Comments**
(12) ***Skin care preparations, (creams, lotions, powder, and sprays).***	(14) ***Skin care preparations, (creams, lotions, powder, and sprays).***	(12) ***Skin care preparations, (creams, liquids, lotions, gels, oils, pads, powders, and sprays).***	(12) ***Skin care preparations, (creams, liquids, lotions, gels, oils, pads, powders, and sprays).***	PCPC proposes FDA add the other specified examples in parentheses.
(i) Cleansing (cold creams, cleansing lotions, liquids, and pads).	(a) Cleansing (cold creams, cleansing lotions, liquids, and pads).	(a) Face cleansing (cold creams, cleansing lotions, exfoliators, liquids, pads, and wipes).	(a) Face cleansing (cold creams, cleansing lotions, exfoliators, liquids, pads, and wipes).	PCPC proposes FDA clarifying that this category is for face products and add "exfoliators" and “wipes.”
		1. Wipes	1. Wipes	PCPC proposes FDA add.
		2. Other	2. Other	
(ii) Depilatories.	(b) Depilatories.	(b) Depilatories.	(b) Depilatories.	
(iii) Face and neck (excluding shaving preparations).	(c) Face and neck (excluding shaving preparations).	(c) Face and neck (excluding shaving preparations).	(c) Face and neck (excluding shaving preparations).	
	1. Leave-on.		1. Sprays.	Companies would likely not file rinse-off products in this category. Such products would be listed in one of the cleansing categories. Instead, PCPC proposes FDA add sprays for scenario #2.
	2. Rinse-off.		2. Other (creams, gels, oils, etc.).	

VCRP Categories 3.26.23	**FDA Draft Guidance 8.7.23**	**PCPC Proposal w/ Exposure Categories (Scenario #1)**	**PCPC Proposal w/o Exposure Categories (Scenario #2)**	**PCPC Comments**
(iv) Body and hand (excluding shaving preparations).	(d) Body and hand (excluding shaving preparations).	(d) Body (excluding shaving preparations).	(d) Body (excluding shaving preparations).	PCPC proposes FDA move "hand" into its own category below.
	1. Leave-on.		1. Sprays.	Companies would likely not file rinse-off products in this category. Such products would be listed in one of the cleansing categories. Instead, PCPC proposes FDA add sprays for scenario #2.
	2. Rinse-off.		2. Other (creams, gels, oils, etc.).	
		(e) Lip.	(e) Lip.	PCPC proposes FDA add for better exposure information.
		(f) Hand.	(f) Hand.	PCPC proposes FDA add for better exposure information.
(v) Foot powders and sprays.	(e) Foot powders and sprays.	(g) Foot.	(g) Foot.	PCPC proposes FDA clarify that any foot skin care products be listed in this category.
			1. Sprays.	PCPC agrees with CIR's suggestion.
			2. Powders.	
			3. Other (creams, gels, oils, etc.).	
(vi) Moisturizing.	(f) Moisturizing.			PCPC proposes FDA remove and replace with proposed face/neck/body/lip/hand/foot categories to improve exposure information.

VCRP Categories 3.26.23	**FDA Draft Guidance 8.7.23**	**PCPC Proposal w/ Exposure Categories (Scenario #1)**	**PCPC Proposal w/o Exposure Categories (Scenario #2)**	**PCPC Comments**
(vii) Night.	(g) Night.			PCPC proposes FDA remove and replace with proposed face/neck/body/lip/hand/foot categories to improve exposure information.
(viii) Paste masks (mud packs).	(h) Paste masks (mud packs).	(h) Paste masks (mud packs).	(h) Paste masks (mud packs).	
(ix) Skin fresheners.	(i) Skin fresheners.			PCPC proposes FDA remove and replace with proposed face/neck/body/lip/hand/foot categories to improve exposure information.
		(i) Skin care oils.	(i) Skin care oils.	PCPC proposes FDA add.
(x) Other skin care preparations.	(j) Other skin care preparations.	(j) Other skin care preparations.	(j) Other skin care preparations.	
	1. Leave-on.	1. Leave-on.	1. Leave-on.	
	2. Rinse-off.	2. Rinse-off.	2. Rinse-off.	
(13) ***Suntan preparations.***	(15) ***Suntan preparations.***	(13) ***Suntan preparations.***	(15) ***Suntan preparations.***	
(i) Suntan gels, creams, and liquids.	(a) Suntan gels, creams, and liquids.	(a) Suntan gels, creams, and liquids.	(a) Suntan gels, creams, and liquids.	
(ii) Indoor tanning preparations.	(b) Indoor tanning preparations.	(b) Sunless tanning preparations.	(b) Sunless tanning preparations.	PCPC proposes FDA clarify "indoor" to "sunless."
	1. Traditional applications (creams, lotions, etc.).		1. Traditional applications (creams, lotions, etc.).	Not necessary in scenario #1.

VCRP Categories 3.26.23	**FDA Draft Guidance 8.7.23**	**PCPC Proposal w/ Exposure Categories (Scenario #1)**	**PCPC Proposal w/o Exposure Categories (Scenario #2)**	**PCPC Comments**
	2. Airbrush applications.		2. Airbrush applications.	
	3. Spray applications.		3. Spray applications.	
	4. Professional airbrush tanning applications.			Not necessary as "Professional" is optional question on form.
	5. Professional spray tanning applications.			
(iii) Other suntan preparations.	(c) Other suntan preparations.	(c) Other suntan preparations.	(c) Other suntan preparations.	
	(17) ***Other preparations*** *(i.e., those preparations that do not fit another category)***.**	(15) ***Other preparations*** *(i.e., those preparations that do not fit another category)***.**	(17) ***Other preparations*** *(i.e., those preparations that do not fit another category)***.**	
		1. Leave-on.	1. Leave-on.	PCPC agrees with CIR's suggestion.
		2. Rinse-off.	2. Rinse-off.	