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PCPC Comments on FDA's Registration and Listing of Cosmetic Product Facilities and Products; Guidance for Industry; Availability (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; Availability" published in the Federal Register on December 19, 2023, under Docket No. FDA-2023-D-1716 (the "Guidance") and "FDA Announces Launch of Cosmetics Direct for Electronic Registration and Listing of Cosmetic Product Facilities and Products" published as a constituent update on December 18, 2023. FDA also announced the availability of SPL Xforms, Form FDA 5066 "Registration of Cosmetic Product Facility," and Form FDA 5067 "Cosmetic Product Listing" on January 9, 2024.

PCPC previously submitted public comments on FDA's cosmetic registration and listing program in 2023 on June 30, September 7, October 18, and November 28. This submission supplements PCPC's previous comments.

Introduction

PCPC congratulates FDA on the successful launch of Cosmetics Direct on December 18, 2023, and before the one-year anniversary of the passage of the Modernization of Cosmetics Regulation Act (MoCRA) of 2022. We appreciate FDA's efforts to develop this platform and all the supporting documentation that will assist industry to understand and comply with the new requirements.

Already, many of our members have been able to submit at least some of their facility registrations and products listings on this new platform. However, we have been informed of several very critical inefficiencies in Cosmetics Direct that could be barriers for the successful completion of certain registrations and listings, and thus they will be critical for FDA to address in order to support the registration of all cosmetic facilities and listing of all cosmetic products by the compliance policy deadline of July 1, 2024. Certain issues are negatively impacting the efficiency of the Cosmetics Direct system for all users. Some of the issues are posing an unreasonable burden for companies seeking to list cosmetic products that were manufactured or processed by a contract facility. We note that several of these issues were previously raised by PCPC in our public comments and, we understand, by certain companies that participated in

FDA's pilot of Cosmetics Direct from December 11-15, 2023.

In sections below, we reflect on several of the changes to the Guidance and features in Cosmetics Direct that were requested by PCPC. We request certain changes to the new "Frequently Asked Questions and Answers" section of the Guidance, including to address our concerns with validation on brand-product names in Cosmetics Direct and whether laboratories that perform batch release testing are facilities subject to registration. We repeat our request for changes to certain fields, including that the "Fragrance or Flavor" field must be removed as it is redundant and has resulted in many errors and inefficiencies. We also repeat our concerns with certain validation codes that are increasing the burden of registration and listing, and are unnecessary, including validation that prevents the submission of listings based on what another company has or has not submitted on a registration. Finally, we request certain enhancements for Cosmetics Direct and repeat our request that FDA offer training.

Table of Contents for Technical Feedback

Final Guidance

PCPC appreciates that FDA has finalized the Guidance originally published as a draft on August 8, 2023. The final Guidance includes several important clarifications requested by PCPC:

- Improved directions for requesting an FEI number.
- Clarification that a responsible person whose products are manufactured or processed at a contract facility may submit the facility registration for such facility.
- Clarification that the responsible person must submit a cosmetic product listing, or ensure such submission is made.
- Defined U.S. Agent using the same FDA definition used for other FDA regulatored industries.

Seperately, FDA has published a User's Guide for Cosmetics Direct, which PCPC requested in our October 2023 comments. We have on several occasions leveraged this User's Guide to help our members learn how to use Cosmetics Direct.

Confidential Fields

As discussed in our September 2023 comments, we request that FDA confirm in the Guidance the confidentiality of responsible person(s) on facility registrations, and that this information will not be shared between different responsible persons who may register the same contract facilities where their cosmetic products are manufactured or processed, or list cosmetic products from such facilities. The Freedom of Information Act (FOIA) Exemption 4 protects commercial information where such information relates to business or trade, and where disclosure of such information would create a competitive disadvantage. The identity of a responsible person on the facility registration meets both these criteria, and as such, is information that a company would not readily divulge to the public or to its competitors. While we are confident that such information should be protected under the spirit of the fourth FOIA exemption, we would appreciate explicit confirmation of these privacy protections in the Guidance.

Feedback on Frequently Asked Questions and Answers

We appreciate FDA's addition of APPENDIX B: Frequently Asked Questions and Answers (FAQ) to the final guidance, and the opportunity to consult on this section through January 18, 2024. The FAQ includes many helpful answers that we have also often heard from our members and other stakeholders. We support the addition of many of the draft answers in Appendix B. We offer the following feedback on those questions that address the differences between brand name and product name, and whether laboratories that perform batch release testing are a facility subject to registration. We also request that FDA address certain additional questions that PCPC frequently receives and which we understand to be very important for companies seeking to comply with their registration and listing obligations under MoCRA.

Is the brand name the same as the product name?

We agree with FDA's draft answer that brand name and product name are not the same. However, we are concerned that this position may be contradicted by a validation code in Cosmetics Direct/SPL that appears to require all product names entered on listings include, as a subset, the exact brand name that was previously entered on all related facility registrations. We hightlight later in this letter how this validation code is making it much more difficult for companies to submit their product listings, and we offer our requested solution.

Does a laboratory that performs cosmetic product batch release testing need to register?

We request that FDA modify the draft answer asserting that laboratories that perform cosmetic product batch release testing would meet the definition of a facility and would be subject to registration. As noted in our October 2023 comments in response to FDA's "Manufacturing and Processing of a Cosmetic Product" definition, section 604(3)(B) of the FD&C Act exempts from the facility definition "an establishment that manufactures or processes cosmetic products that are solely for use in a research or evaluation, including for production testing and not offered for retail sale." Per this definition, a laboratory performing batch release testing would be exempt from the facility definition, as batch release testing is an evaluation activity performed as part of the production process. Samples are discarded after testing and are not offered for retail sale. We also presume that FDA has a much greater interest in the registration of non-exempt establishments that made a cosmetic product.

Given the statutory language and the nature of batch release testing, it is our understanding that third party laboratories performing such testing do not anticipate the need to register their facilities. If FDA were to finalize this position, responsible persons would need to inform all such laboratories of this requirement, ensure their willingness to comply, coordinate the completion of all applicable FEI requests and registrations, and add FEI numbers to all

applicable listings. The time and costs needed to accomplish all of these unforseen tasks would make meeting a July 1, 2024 deadline incredibly challenging, if possible at all.

Moreover, some companies have many laboratories under contract for batch release testing on an "as needed" basis, and these may never actually be tasked to test any samples or only a few for a short period of time. We are concerned that responsible persons may feel obligated to enter all such laboratories on their listings, potentially multiple laboratories per listing, out of an abundance of caution, even if such laboratories never test the product in question.

The situation described above will be further complicated if FDA does not allow for discretion for facilities that will have stopped manufacturing or processing cosmetics products by July 1, 2024 (p. 5), nor remove validation based on what other companies submit in Cosmetics Direct (p. 8).

Does a contract facility that stopped manufacturing or processing cosmetic products by July 1, 2024, need to be registered?

As discussed in our November 2023 comments, we believe it is necessary for FDA to clarify that contract facilities that will have stopped manufacturing or processing cosmetic products by July 1, 2024, do not need to be registered even if there may still be products on the market that were manufactured or processed by the contract facility before this date. PCPC's members want to ensure compliance with all MoCRA requirements, including the registration of their facilities. 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 PCPC members have determined that they cannot take responsibility for registering a facility with which they no longer have a contractual relationship.

If FDA does not address our request in this letter to remove validation based on what other companies submit in Cosmetics Direct (p. 8), then it may be impossible for responsible persons to submit their product listings related to a contract facility that have stopped manufacturing or processing cosmetic products by July 1, 2024, and have not been registered.

Does a cosmetic product that has not been placed into interstate commerce by the responsible person on or after December 29, 2022, need to be listed?

As discussed in our November 2023 comments, we believe it is necessary for FDA to 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. Again, PCPC's members want to ensure compliance with all MoCRA requirements, including the listing of their cosmetic products, but 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, for instance, may not inform the responsible person whether a cosmetic product, discontinued by the responsible person before December 29, 2022, was marketed at any time after this date. If FDA were to expect the listing of such products, then a responsible person may have no way of fully ensuring compliance. Attempts to list all cosmetic products that had been discontinued throughout the several years preceding MoCRA would be unnecessarily burdensome and not necessarily productive. We presume that FDA has a much greater interest in cosmetic products that have not been discontinued, and these should be prioritized.

Fields That Need Certain Updates

"Fragrance or Flavor" should be removed

As discussed in our October 2023 comments, we request that FDA not include the "Fragrance or Flavor" field on the product listing form. Section 607(c)(4)(A)(iv) of the FD&C Act only requires the entry of ingredient names declared on cosmetic product labels, including "fragrance" and "flavor," as part of the list of ingredients entered on such listing, which is a field that FDA has also included on the listing form. The FD&C Act does not authorize FDA to require this field in addition to the list of ingredients field, and its inclusion is unnecessarily duplicative.

Furthermore, we have been informed by our members of many errors and inefficiencies that are negatively impacting every listing submited in Cosmetics Direct, due to the inclusion of the "Fragrance or Flavor" field. We believe all such issues would be resolved if FDA removes this field from the listing form. If removed, users would continue to enter information on the presence of fragrance and flavor ingredients on the Ingredient page as required by the FD&C Act. Experiences noted by PCPC members:

- If a user attempts to go to the Ingredient page before responding to the "Fragrance or Flavor" field, they are prevented from doing so.
- If a user selects any response in the "Fragrance or Flavor" field on the Product page, then they are prompted to read and close a pop-up message, which is an additional step that is extending the amount of time necessary to complete every listing in Cosmetics Direct. It is also unnecessary and duplicative, as the same information is available to users as a tooltip when hovering a cursor over the field name.
- If a user selects "N/A," then attempts to enter "Fragrance," etc. on the Ingredients page they receive an error message that requires them to go back to the Product page to pick "Fragrance," etc. from that drop down menu.
- If a user selects "Fragrance," etc., then "Fragrance" will be automatically entered on the Ingredient page as the first ingredient. However, fragrance, etc. ingredients are very rarely the first ingredient declared on labels. In almost all cases where a cosmetic product contains a fragrance, etc. ingredient, users need to change the order of such ingredients on the Ingredient page to reflect the order declared on the label.

- If a user attempts to delete "Fragrance," etc. from the Ingredient page, they are prevented from doing so and must go back to the Product page to pick "N/A," etc. from the drop down menu.
- If a user makes any change to the "Fragrance or Flavor" field on the Product page, all other ingredients previously entered on the Ingredient page will be deleted.
- If a user selects "N/A" from in the "Fragrance or Flavor" field on the Product page and then uploads an Ingredient File with "Fragrance," etc. on the Ingredient page, the "N/A" selection does not automatically update. Users must then go back to the Product page to pick "Fragrance," etc. from the drop down menu, which will then delete all other entered ingredients from the Ingredient page.
- It is not possible to submit an accurate listing if an alternative version of "Fragrance," etc. is declared on the label, e.g., "Fragrance (parfum)," etc., which we understand is very common for products that are labeled for both U.S. and certain foreign markets. In such cases, users must decide between selecting "N/A" and entering "Fragrance (parfum)," etc., even if it is accurate to select "Fragrance" on the Product page, or enter both "Fragrance" and "Fragrance (parfum)," etc. on the Ingredient page even if this is not how such ingredients are declared on the label.
- It is not possible to submit an accurate listing if all fragrance ingredients are declared on the label individually, e.g., "Citronellol," etc., and not as "Fragrance." In such cases, users must decide between selecting "N/A" and entering "Citronellol," etc., even if it is accurate to select "Fragrance" on the Product page, or enter both "Fragrance" and "Citronellol," etc. on the Ingredient page even if this is not how such ingredients are declared on the label.

"Name of the Owner and/or Operator of the Facility" must be optional

As discussed in our September 2023 comments, we request that FDA update the "Name of the Owner and/or Operator of the Facility" field on the facility registration form so that it is identified as optional. FDA is not authorized to require this information by section 607 of the FD&C Act, nor any other law or regulation that has been identified by the Agency. PCPC continues to support FDA including this as an optional field.

Increase "Ingredient Name" field character limit to 2100+

We request that FDA increase the character limit for the Ingredient Name field in Cosmetics Direct to at least 2100. We understand that the character limit is currently set to approximately 430. While the majority of names do no exceed this threshold, there are some INCI names that do. As of today, there are 32 INCI names with over 430 characters. The longest INCI name has 2046 characters (with spaces). The character limit should be increased to accommodate these and any other large ingredient names that may need to be entered.

Burdensome and Unnecessary Validation Codes

We are concerned with certain validation codes in Cosmetics Direct that are making it much more difficult to submit product listings, facility registrations, and (in the future) renewals and updates of product listings. We request that FDA consider the issues that are being caused by these validation codes and to resolve such issues. PCPC does not have expertise to offer on SPL validation codes – FDA would know best in this regard – but we have looked through the SPL Guide to identify the following codes that may be causing the problems identified by our members.

Users should not be prevented from listing a product based on what another company has or has not submitted on a facility registration

PCPC member companies have informed us that Cosmetics Direct/SPL includes validation code that prevents the submission of product listings until after the submission of each related facility registration, and only if the listing includes the brand-product and responsible person names exactly as entered in the registration. In many cases, related registrations and listings will be submitted by different companies who must now undertake very burdensome, unnecessary, and, in our view, unreasonsable coordination to assure data entered matches exactly. In this way, the validation code is posing significant and unanticipated burdens on the industry, well beyond any other aspect of FDA's registration and listing program.

Some of our member companies have dozens of contract facilities with which they would have to coordinate such information. In fact, we believe FDA may have recognized this problem, in part, when in November 2023, FDA removed from section 36.1.6.5 of the updated SPL Guide the proposed validation code from the October 2023 SPL Guide that would have required that the product listing have the "same product brand name" as the facility registration. PCPC thanked FDA for this change in our November 2023 comments. However, we now know that this validation code was never removed from Cosmetics Direct/SPL.

To facilitate the completion of all product listings before FDA's July 1, 2024, deadline and on an ongoing basis, we recommend that FDA remove all validation code from Cosmetics Direct/SPL that prevents the submission of a product listing based on what was or has not been entered on a facility registration.

It will also be necessary for FDA to remove this validation code to facilitate the submission of all product listings by the July 1, 2024, compliance deadline, as certain facility owner/operators may not complete their registrations until immediately before this date.

Validation code identified by PCPC as a concern:

- 36.1.6.5 If the facility has no small business designation, then there is an active facility

registration for this facility with a cosmetic product.
- (Oct. SPL) 36.1.6.5 If there is a SPL SMALLBUSINESS designation and if the facility has an id (FEI), then there is an active facility registration for this facility with the same product brand name and their respective "responsible person" as the labeler of this file.
- 36.1.6.6 Each listed product is linked from at least one facility.

Users should not be required to re-enter information on the registration form (brand name, responsible person name, and product categories)

As discussed in our October 2023 comments, we request that FDA not require the re-entry of any information on the registration form associated with the FEI number entered on such form, which would be submitted to the Agency as part of a product listing. This would include the brand names of cosmetic products manufactured or processed at each facility, responsible person name, and product category code. Such information could be much more efficiently obtained if required only on the product listing. This would lower the burden of the registration and listing activities and help limit any unintentional errors on both forms. If FDA continues to require the re-entry of such fields on the facility registration form, then responsible persons will need to request that their contract manufacturers share confidential business information about their other clients (e.g., brand names, product categories, responsible person names, etc.) for the purpose of registering such facilities. This is also an unnecessarily duplicative requirement that would not result in FDA receiving any additional information that would be useful for the Agency's purposes.

Validation code identified by PCPC as a concern:

- 35.2.1.2 If the document is a Cosmetic Facility Registration (103573-2), Cosmetic Facility Registration - Amendment (X8888-1), or Cosmetic Facility Registration – Biennial Renewal (X8888-4), then there is a document body.
- 35.2.1.3 The document body contains one section
- 35.2.1.4 The one section contains the product data elements
- 35.2.2.1 There is a name, i.e., the brand name under which the cosmetic product is sold.
- 35.2.2.3 There are one or more cosmetic product category codes (asSpecializedKind element) with a code (see Section 3.4.3).
- 35.2.3.1 There is one responsible person (organization).

Users should not be prevented from registering a contract facility that was previously registered by a company that is a competitor

As discussed in our September 2023 comments, we request that FDA not prohibit the submission of duplicate facility registrations under the same FEI number. The FD&C Act does not preclude the facility owner and operator or any responsible person(s) whose products are manufactured or processed at a facility from submitting a duplicate facility registration. Most companies will not want to submit a duplicate facility registration to FDA and PCPC is advising our members to

avoid doing so. However, a company may feel obligated to do so if they are unable to confirm that the facility that they would like to register is and will continue to be registered by a different company (e.g., facility owner or operator, responsible person whose products are also manufactured or processed at such facility, etc.).

If FDA does not address this request nor our other request in this letter on the removal of validation based on what other companies submit in Cosmetics Direct (p. 8), then it will be impossible for users to submit their product listings if they are related to a contract facility that was registered by a competitor who is unwilling to add their brand name, etc. to the registration.

Validation code identified by PCPC as a concern:

- 36.1.5.5 The id (FEI) is not used for any other facilities in the file.

Users should not be prevented from modifying any field when renewing or updating a product listing (product name, ingredients, responsible person, and product categories)

As discussed in our November 2023 comments, we request that FDA modify Cosmetics Direct/SPL so that companies can update any required field on their previously submitted product listings. We are concerned that Cosmetics Direct does not permit the renewal or update of a product listing unless the product name, ingredients, responsible person, and product categories exactly match the originally submitted listing. Users are thus not 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 information in these fields.

We understand that updates to the information in these fields are common, especially for ingredients. When these errors occur, responsible persons must 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 validation appears to be unnecessarily burdensome.

Validation code identified by PCPC as a concern:

- 36.2.2.12 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.
- 36.2.2.13 Cosmetic product category matches the cosmetic product category previously assigned to this listing number.

Requests for Enhancements to Cosmetics Direct

PCPC appreciates that FDA has included many user-friendly features in Cosmetics Direct. The platform includes several important features requested by PCPC:

- Immediate account access and multiple users
- Option to submit registrations and listing in bulk via an SPL file
- Table view of all draft and submitted registrations and listings
- Ability to add any ingredient/INCI names
- Option to upload ingredients using an Excel template
- Modified the FEI exemption field on the listing form to: "Is the facility where the product is manufactured or processed exempt from registration (for example because it is a small business)?"
- Option to clone all product fields

We support FDA's efforts to develop additional enhancements for Cosmetics Direct to support the efficient submission of registrations and listings. We request that FDA consider the following suggestions.

Publish a Cosmetic Establishment Current Registration Site

As discussed in our September 2023 comments, we request that FDA establish a search function or some other means to assist stakeholders to confirm that a cosmetic facility is registered with FDA. The FEI search portal can only be used to confirm that a facility has an FEI number, but this is not confirmation that a facility is registered with FDA for a specific regulated activity. Facilities owners/operators, responsible persons, and potentially other stakeholders may have an obligation to confirm that a facility where their cosmetic products are manufactured or processed is currently registered with FDA for that activity. FDA should consider creating something similar to the Drug Establishments Current Registration Site for registered cosmetic facilities. The cosmetic establishment current registration site should be limited to the fields necessary to confirm that a facility is registered for cosmetic operations: firm name, FEI number, business operations, address, and registration expiration date.

Add search by Product Listing Number and Excel download to Cosmetics Direct table view

We appreciate that the table view in Cosmetics Direct includes several search options that will help companies manage their registrations and listings, including facility name, facility FEI, responsible person name, product name, last modified user, and last modified date. However, missing from the list of options is the ability to search by Product Listing Number. We understand that many companies will need to manage their listings using this number, particularly if they have many products with similar names. We request that FDA add this option to Cosmetics Direct.

We understand that many companies would like to be able to download from the table view all registrations and listings in Cosmetics Direct. This would help users compare their filings against their company records to help ensure that information in Cosmetics Direct is accurate, complete, and up to date. We request that FDA add this option to Cosmetics Direct.

Add option for bulk renewals

As discussed in our October 2023 comments, we request that FDA develop a process to facilitate the abbreviated renewal of registrations and listings in bulk in accordance with Sec. 607(a)(5) and Sec. 607(c)(3) of the FD&C Act. Such a process would allow for the selection of all registrations and listings with no updates that are to be renewed. Currently, Cosmetics Direct only permits the renewal of individual registration and listing submissions, which would be significantly less efficient than a bulk renewal process.

We note that FDA permits the bulk renewal of product listings in CDER Direct using the "Blanket No Changes Certification." We request that FDA create a similar option for both registrations and listings in Cosmetics Direct.

Add Title field (from draft screenshots)

We request that FDA add the optional "Title" field for product listings that previously appeared in the Cosmetics Direct draft screenshots (listing table view and listing form) published in Sept. 2023. It is no longer present in Cosmetic Direct. This field would be useful to enter a company internal code (e.g., formulation code) or other identifier to help companies organize their submissions.

(If still applicable) Add option to upload brand information using a template

If FDA continues to prevent the submission of listings based on what was submitted on a registration (p. 8) and to require the re-entry of information on the registration form (p. 9), which we oppose, then we request FDA add a new option that would enable the bulk entry of brand name, responsible person name, and product categories on the registration form. We expect updates to these fields will be made on a very frequent basis to accommodate the listing of new products and this option could help streamline the process. We recommend the user-friendly Ingredient File from the listing form as a possible solution to address this need.

Other Cosmetics Direct Enhancements

We request that FDA add the following additional enhancements to Cosmetics Direct:

- Ability to delete and discontinue a product listing – these options do not appear to be available in Cosmetics Direct
- Allow users to reset their passwords immediately after being locked out of their account –

there is currently a 30-minute lock out period
- Extend the 30-minute inactivity log-off period to at least 1 hour
- Ability to change the columns available in the table view (e.g., "Created by" instead of "Last Modified User," etc.)
- Allow for the optional entry of Facility Name/Address when the FEI number is entered on the listing form, so that users can use this information to help track their submissions. Alternatively, automatically display the Facility Name/Address when the FEI number is entered.
- Record of all changes made to registrations and listings

Training

Following the launch of Cosmetics Direct and Xforms, PCPC would like to re-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 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 United States. While the SPL Guide will be critical to help many of these companies learn how to create an SPL-formatted submission, we believe the length and complexity of that 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.

SPL Xforms

While we appreciate FDA's announcement on the availability of the alternative electronic submission portal SPL Xforms for cosmetics, it is our understanding that our members have not been able to create new cosmetic facility registration nor cosmetic product listings from the templates that are currently available in Xforms. There does not yet appear to be a template for either form in Xforms. There is a template for "cosmetics" (58474-8), but it does not include most fields from the cosmetic registration and listing forms. We had expected to see templates for the forms with the codes 103573-2 (registration), 103572-4 (listing), and the related update/renewal forms. It appears possible to load SPL forms for cosmetic registration and listing that were developed outside of Xforms (e.g., in Cosmetics Direct), however Xforms only appears to display a subset of fields from these forms and so it is not possible to edit all fields. We request that FDA consider this issue, publish the relevant templates in Xforms or make any other necessary changes, and offer training on Xforms to help companies find and fill-in the cosmetic registration and listing templates.

Conclusion

Thank you for considering these comments on FDA's final Guidance and launch of Cosmetics Direct. 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

Thomas Myers
President & CEO