FEEDBACK ON THE CONSOLIDATED COMMENTS

Virtual Public Consultation
07 September 2022 | 1PM - 3PM

Proposed issuance *"Updated Guidelines on Product Information File (PIF) for Cosmetic Products Repealing FDA Circular No. 2018-001 'Reiterating the Mandatory Implementation of Article 8 of the ASEAN Cosmetic Directive, Product Information'"*

Question / Comment no. 1

Keeping retention samples for every batch of all products is costly on our end, especially that we have imported products with limited number of samples only. If ever, will a letter of request for exemption/consideration regarding the submission of retention sample suffice to comply with the PIF?

We wish to clarify that it is not all the time that a retention sample is requested to be submitted to the FDA. However, retention samples shall be retained by the MAH to provide a sample for analytical testing and a specimen of the fully finished product. The retention samples serve as a record of the batch of finished product and can be assessed in the event of, for example, a quality complaint, a query relating to compliance with the marketing authorization, or a labelling/packaging query.

Question / Comment no. 2

Need clarification on the On-pack Product Claim Support since it was stated in Parts I and IV. Is there a difference of the two in part I versus part IV? If none, in what part of the PIF should we need to include the On-pack Product Claim Support?

The PIF Part I contains the administrative documents and key summary information that are specific to a single product. This part is expected to provide an ample overview of the finished product.

The complete report/rationale/justification of on-pack claim support can be found in Part IV of the PIF.

Question / Comment no. 3

How many retention samples per batch do you require for us to retain?

The collection of the retention sample shall be according to the sampling procedure defined in the SOP of the MAH. The size of a retention sample should be sufficient to allow for at least two confirmatory analyses.

Question / Comment no. 4

For single component products, I would like to ask if the assay from raw materials would be valid as claim also for the FG so we no longer need to subject the FG to testing.

In all cases, the finished product shall be subjected to analysis and testing. The raw material testing shall be independent from the finished product testing.

Question / Comment no. 5 (1/2)

How do we protect the confidentiality of the information that is provided especially that we deal with trade secret information – mainly on information security and access to information of intended recipients especially now that hacking and other scam activities are very prevalent? Also, there have been instances where we are receiving some notices that are intended for other companies.

The FDA, as a national government agency, upholds and complies with the Data Privacy and Intellectual Property Laws. All employees of the FDA are bound by a Confidentiality Undertaking following its existing administrative and human resource rules and regulations.

Question / Comment no. 5 (2/2)

All documents transmitted to the FDA during the PIF Audit are treated with utmost confidentiality and are used solely for the purposes of the audit and the regulatory actions that follow.

The FDA adheres to cybersecurity policies & protocols following the Department of Information and Communications Technology (DICT) and the Data Privacy policies of the National Privacy Commission (NPC).

Question / Comment no. 6

It would be a good approach to focus on the highest impact on the quality, safety and sincerity of products in the market especially when the number of requests or notices is at hundreds where it may be difficult for the MAH, inspectors and officers to review all the documents. There should be a realistic timeline and efficient approach as well on reviewing the document.

For context, the post-market surveillance activities of the FDA conducted for cosmetic products entail a risk-based approach. Hence, in practice, the FDA prioritizes PIF audits of cosmetic products with actual in-market issues and products posing significant health risks.

Question / Comment no. 7 (1/2)

We would like to kindly submit our humble appeal to consider retention samples made available upon formal request from CCRR accompanied by a signed letter in the following scenarios:

- Consumer complaints highlighting adverse reaction/event caused by our product
- Result of sample testing e.g., presence of heavy metal/s beyond ASEAN Limit of Contaminants
- Misleading claims that pose threat to consumer health and safety

Question / Comment no. 7 (2/2)

Pursuant to FDA Circular 2018-001, the retention samples for every batch of cosmetic product manufactured/ distributed shall be kept. We wish to clarify that it is not all the time that a retention sample is requested to be submitted to the FDA. However, retention samples shall be retained by the MAH to provide a sample for analytical testing and a specimen of the fully finished product. The retention samples serve as a record of the batch of finished product and can be assessed in the event of, for example, a quality complaint, a query relating to compliance with the marketing authorization, or a labelling/packaging query.

Should there be specific recommendations or proposals coming from marketing authorization applicants, cosmetic establishments, researchers, etc. on the retention sample requirement, the Center is open to receive such for further review. On such recommendations or proposals, a copy of the standard or reference and a letter-request from the proponent should be submitted to the FDA.

Question / Comment no. 8

Please clarify the scope of distributors that are included in the considerations. Since only the MAHs will undergo PIF audit, will it be correct to assume that all distributors (regardless of activity or scale) will be given the said considerations.

Yes, this is to confirm that all distributors (regardless of activity or scale) will be given consideration, wherein Part I of the PIF shall be required, at the minimum, to be available at the address of the MAH for the purposes of initial PIF Audits.

Question / Comment no. 9

Please clarify what “other information” may be requested and define the “reasonable timeframe” that will be given. Does this pertain to documents outside of the PIF requirements?

“Other information” refers to supplementary information relevant to confirm the quality, safety, or claimed benefit issue of the cosmetic product being evaluated during the PIF Audit. The “reasonable timeframe” may range from fifteen to sixty (15-60) calendar days, depending on the urgency of the audit and classification of the deficiency/ies.

Question / Comment no. 10

For routine audits, suggest to set the timeline to send NOA to “at least one month before the date of audit” to make the timings more defined.

The Notice of Audit shall be sent *preferably* one (1) month prior to the date of the audit. However, should the MAH require special arrangements, such must be communicated by the MAH to the FDA once they have received a copy of the NOA in order to prevent unduly delaying regulatory activities.

Question / Comment no. 11

Raising concern on cybersecurity for both synchronous audit via virtual meeting/ conferencing platforms. Use of free platforms like Google and Zoom may not be the most ideal venue to use. Hoping FDA will ensure sufficient IT infrastructure is in place to help secure this initiative.

The FDA adheres to cybersecurity policies & protocols following the Department of Information and Communications Technology (DICT) and the Data Privacy policies of the National Privacy Commission (NPC). The FDA currently holds premium subscriptions with secure meeting platforms. For remote PIF audits, the FDA shall use such secure platforms.

Question / Comment no. 12

On collection of samples, in case a specific batch of product is required, kindly provide sufficient time to secure these samples from the sources.

Submission of samples may range from fifteen to sixty (15-60) calendar days, depending on the urgency of the audit and classification of the deficiency/ies. Should the MAH require special arrangements, such must be communicated by the MAH to the FDA.

Question / Comment no. 13

For incomplete PIF, it is expected that we will have 15-60 calendar days to provide corrective action and other documents required, hence serving as a compliance period post-audit. If this is the case, we appeal that further regulatory actions be done in case the MAH fails to comply within the said period.

Consistent with the proposed updated guidelines, the FDA shall impose subsequent regulatory actions upon failure of the MAH to sufficiently comply and address the deficiencies during the provided compliance period.

Question / Comment no. 14 (1/3)

Clarification on the classification of deficiency – is the type of deficiency identified during the course of the audit or after the compliance period that FDA will give after the audit?

If FDA expects that PIF Part I is available at minimum during the audit, how come there are scenarios classified under Critical deficiencies related to documents found outside of PIF Part I?

Suggestion that the deficiency classification and subsequent resolution/regulatory action will be identified/decided after the compliance period provided by FDA, especially in cases of ad hoc audits.

Suggestion to reconsider the scenarios listed under Critical deficiency, especially on documentations pertaining to raw materials, since these documents would need to be coordinated with the suppliers and may be challenging in some cases to have available on file.

Question / Comment no. 14 (2/3)

The deficiencies will be classified during the PIF Audit, however, subject to further review of the submitted compliance, classifications may be updated (escalated or lowered) following the provided definitions.

Please refer to the general rule which states that "In general, the complete PIF must be made available during PIF Audits, whether routine or ad hoc, onsite or offsite." The deficiencies will be identified depending on the type of establishment audited. Wherein, manufacturers and traders are required to present the complete PIF of the cosmetic product, while, considerations will be given to Distributors and Micro, Small and Medium Enterprises (MSMEs) as to the completeness of the PIF.

Question / Comment no. 14 (3/3)

As stated, the list is non-exhaustive and other observations may be added, removed, or re-classified as appropriate.

However, where the “incompleteness” of the PIF has produced, or may lead to, a significant risk of producing either a product which is harmful to humans, it shall be classified under a Critical Deficiency.

Question / Comment no. 15 (1/2)

Can we request FDA to share their protocol in case the FDA auditor lose their laptop (with downloaded / uploaded copies of proprietary documents) or printed company documents that they requested from the audited company after on-site audit?

The FDA adheres to cybersecurity policies & protocols following the Department of Information and Communications Technology (DICT) and the Data Privacy policies of the National Privacy Commission (NPC). All employees of the FDA are bound by a Confidentiality Undertaking following its existing administrative and human resource rules and regulations.

Question / Comment no. 15 (2/2)

All documents transmitted to the FDA during the PIF Audit are treated with utmost confidentiality and are used solely for the purposes of the audit and the regulatory actions that follow. In addition, government property, including laptops, are under inventory management and control.

Should the MAH require special arrangements for the conduct of the PIF Audit, such must be communicated by the MAH to the FDA once they have received a copy of the NOA in order to prevent unduly delaying regulatory activities.

Question / Comment no. 16

Need clarification on the On-pack Product Claim Support since it was stated in Parts I and IV. Is there a difference of the two in part I versus part IV? If none, in what part of the PIF should we need to include the On-pack Product Claim Support? If yes, what are the specific difference of the two that we need to comply for PIF purposes?

The PIF Part I contains the administrative documents and key summary information that are specific to a single product. This part is expected to provide an ample overview of the finished product.

The complete report/rationale/justification of on-pack claim support can be found in Part IV of the PIF.

Question / Comment no. 17

Curriculum vitae of the safety assessor. The safety assessor shall possess qualifications in the field of toxicology, medicine (dermatology), pharmacy and other related fields and shall be suitably trained in the safety assessment of cosmetics. Will FDA specify on the other related fields? Is a license chemist qualified to act as safety assessor?

Related fields include other allied health science courses, provided that he/she is suitably trained in the safety assessment of cosmetics.

THANK YOU!

www.fda.gov.ph

info@fda.gov.ph