FEEDBACK ON THE CONSOLIDATED COMMENTS

Policy Draft for Comments

Proposed issuance "*Further Regulatory Flexibilities for the Implementation of FDA Circular No. 2020-025 "Implementing Guidelines for DOH Administrative Order No. 2019-0019""*

1. HUHS CPR & Label Transitory Period Extension

Question/Comment(s):

- **We appeal to FDA to reconsider granting a 2-years grace period or until 31 December 2025 for the full implementation of registration and complete exhaustion of non-compliant labels. The 1-year extension stipulated in FDA Advisory 2023-2269 may not be sufficient due to the volume of pending clarifications on registration and label requirements and varying lead times for processing/evaluation of applications.**
- **May we kindly request for reconsideration to have a separate transitory period to phase-in labels. Delay the December 31, 2024 deadline of label compliance and exhaustion. Extend Label exhaustion and compliance period for NON GHS label requirements for 2 years from issuance of applicable guidelines and timeline (Label compliance and exhaustion 2 years from December 2026. Effective December 31 2028).**
- **Kindly requesting to allow use of existing label post hoc December 31,2024 to allow ample transitory period.**

Response:

- The FDA is of current view to consider a one-year extension to allow a cumulative 52-month (4 years and 4 months) transitory period by 31 December 2024 for the HUHS registration and labeling requirements. Any further considerations for label exhaustion, in particular, will be subject for further review.

2. Cancellation of LTO

Question/Comment(s):

Part IV. Section A.3. ***"An LTO shall be cancelled if the establishment, upon verification during inspection, is found in violation of relevant rules and regulations, including the absence of a facility."***

- **May we propose to add "after notice and hearing" to observe due process before an LTO is deemed cancelled.**

Response:

- The inquirer is referred to the Penalty Clause of the proposed policy, where the Uniform Rules of Procedure, which inherently includes due process, applies for violations which merit penalties, including suspension, cancellation or revocation of authorizations.

3. Availability of FDA eServices Portal System for HUHS LTO

Question/Comment(s):

- **May we ask the target timing for the eServices Portal System to be available for HUHS LTO renewal applications.**

Response:

- The HUHS licensing module of the FDA eServices Portal System is in the final stages of development. Due to delays, the updated target launch of the system is on the 2nd Quarter of 2024. Please refer to FDA Advisory No. 2024-0543 for more information and guidance.

4. Extension of Validity for HUHS LTO (1/3)

Question/Comment(s):

- **May we clarify on the submission of a notarized letter request and declaration to FDAC as requirement for the extension of the validity of LTOs expiring from 1 November 2023 to 31 March 2024.**
- **Considering there are LTOs that are expired or will expire before the publication of this guideline, may we propose for automatic extension of LTOs expiring from 1 November 2023 to 31 March 2024 without the requirement to submit a notarized letter of request and without prior approval of FDA.**
- **Considering also that the guidelines is still in the process of public consultation, may we propose to extend the LTOs until such time that the eServices Portal System is available to process renewal applications and to also consider the lead time for processing renewal applications via the eServices Portal System.**

4. Extension of Validity for HUHS LTO (2/3)

Response:

- The HUHS licensing module of the eServices Portal System is in the final stages of development. Due to delays, the updated target launch of the system is on the 2nd Quarter of 2024.
- Due to unforeseen delays in the issuance of this proposed policy, the FDA has considered to automatically extend all previously-issued HUHS LTOs expiring before the availability of the system until 30 June 2024 with waived surcharges. Provided that, a letter of intent shall be submitted to the Food and Drug Action Center of the FDA prior to 15 June 2024.
- Please refer to FDA Advisory No. 2024-0543 for more information and guidance.

4. Extension of Validity for HUHS LTO (3/3)

Question/Comment(s):

- **May we suggest a grace period of 60 days for companies to process their LTO renewal applications once the FDA eServices portal is available.**

Response:

- With the consideration of the longer automatic extension of LTO validity until 30 June 2024, there is no need for a 60-day grace period since the timeline for submitting renewal applications would have already accounted for.

5. Retention of HUHS LTO Number Format

Question/Comment(s):

- **May we confirm if the LTO no. as obtained from the e-Portal v2 system will be retained as it transitions to the eServices Portal System**

Response:

- The FDA CCHUHSRR informs that the LTO number that has been assigned to HUHS establishments when they are issued their initial licenses from the FDA ePortal V.2 system will not be retained when they renew their license through FDA eServices Portal System. Upon renewal, there is a possible change of the sequential number but the LTO format remains as: **CCHUHSRR-(region)-HUHS-(type of activity)-Sequence number**.

6. Process for the Renewal of HUHS CPRs

Question/Comment(s):

- **Please clarify what will be the renewal process for CPRs. that will expire on or before end of transitory period. Will there be an extension or validity period for those with registration that had an earlier approval? That is still covered under the transitory period? Will the auto-renewal process via-e-service available by the end of transitory period?**

Response:

- The FDA would like to clarify that the product registration process is currently hosted in the FDA e-Portal V.2 System, it's migration to the FDA eServices Portal is still currently being reviewed. Announcements on the variation and renewal modules for CPR registration via the FDA e-Portal V.2 System will be made in due course, anticipating timelines for the renewal of any expiring CPR.

7. GHS Requirement (1/2)

Question/Comment(s):

- **We propose to postpone GHS compliance implementation and aspects of GHS must not be included in the requirements until a clear GHS Guidelines is created with proper public consultation and sufficient transition plans.**
- **May we propose to develop / create clear GHS guidelines with appropriate public consultations prior to implementation and provide ample transitory period similar to GHS compliance similar to other parts of the world – 5 years UPON ISSUANCE of PH FDA GHS guidelines. The transitory period of 5 years will be allotted for the Companies to build technical capability and capacity, allow suppliers to adjust current SDSs mostly based on GHS v7 or lower, and adjust their systems to generate 1) SDS compliant to GHS – PH FDA specific guidelines and 2) Revised labels to comply with GHS requirements. FDA to consider reviewing applicability of GHS v8 or lower as the version to use while rest of the world's chemicals are on v7 or lower.**

Response:

- The FDA is currently reviewing the guidelines for GHS and will provide updates prior to the end of transitory period 31 December 2024.

7. GHS Requirement (2/2)

Question/Comment(s):

- **We note that there is an ongoing interagency discussion regarding the adoption of the 8th revision of GHS. May FDA confirm the acceptance of GHS rev 7 and its lower versions until the ver. 8 is put into policy and necessary guidelines are released to the Industry.**

Response:

- While awaiting update on the JAO for GHS Version 8 Adoption, lower versions of GHS are allowed until such time that a definite date for mandatory compliance has been set in the anticipated JAO and by FDA.

8. CPR Variation Application (1/3)

Question/Comment(s):

- **May we ask the lead time for FDA in giving clearance to MAH to proceed with the intended variations/s. May we propose to FDA to allow the MAH to implement the variation/s once the letter is submitted to FDAC and without prior clearance from FDA.**

Response:

- While the FDA is yet to release the Citizen's Charter for the HUHS licensing and product registration processes, the Agency intends to align with the ARTA timelines based on the EODB Act, wherein requests for appropriate service shall be processed within three (3) working days for simple transactions, seven (7) working days for complex transactions, or twenty (20) working days for highly technical transactions, from the date the application or request letter is received by the Center.
- Generally, any requests or applications filed with the FDA must be duly acted upon by the appropriate Center or Office accordingly. On that note, the FDA strongly discourages industry stakeholders from implementing any change/s in circumstances of their issued authorizations without prior clearance from the FDA, as any deviation of establishment or health product information from official FDA records shall be ground for suspension, revocation or cancellation of an existing authorization.

8. CPR Variation Application (2/3)

Question/Comment(s):

- **May we propose to clarify if 'shall apply for a CPR variation application once the system is available' means the previously submitted letter of intent become invalidated once the variation application is applied in the system. Premise, letter of intent is submitted, change is implemented. However, should company apply for variation application and therefore waits for FDA approval for the variation, do companies have to stop implementation while waiting for FDA approval? May we propose to only implement the application for variation to FDA to upcoming changes and not to already FDA notified and acknowledged changes – this will eliminate confusion and work duplication.**

Response:

- To clarify, for change/s in the circumstances of a registered product, the FDA clearance shall only be issued if the FDA CCHUHSRR has ascertained that the registered product, given the requested change in circumstance/s, will still be compliant with existing FDA rules, regulations and standards. Once an FDA clearance has been received, the MAH is cleared to proceed with implementing said change/s in product circumstance/s. Once the online application platform for HUHS CPR variation becomes available, the MAH shall submit the variation application together with the documentary requirements as stated in FC 2020-025 to update the product's records in the system. There will be no need to stop the implementation of the changes that have been previously cleared by FDA, provided that no other changes are made to the registered product. Procedural guidelines for the submission of HUHS CPR variation applications including those that have been cleared by FDA will be issued in due time.

8. CPR Variation Application (3/3)

Question/Comment(s):

- **The provision stated that the MAH HOLDER can proceed with the applied changes after the acknowledgment/ clearance is received? Does it mean that when FDAC issued the DTN it is automatically approved? Or the acknowledgement needs to be made by the HUHS evaluator once forwarded by FDAC to the center? Then proceed For the clearance – is it different from that acknowledgement? or it means the center must approved or review the application before the changes are made and implemented?**
- **Propose to clarify if 'received an acknowledgement / clearance from the FDA' means the AOR being issued by FDAC.**

Response:

- The FDAC shall acknowledge the receipt of the request letter submitted by the MAH and shall forward it to the FDA CCHUHSRR who shall then assess the requested change in product circumstance/s for its compliance with existing HUHS regulations. Once compliance has been ascertained, the FDA CCHUHSRR shall issue the FDA clearance.
- The acknowledgment received from FDAC is only a notification of receipt of applications or requests but will still be forwarded to the concerned Center for appropriate action and final decision on the matter.

9. Notice of Deficiency (NOD) (1/5)

Question/Comment(s):

- **We note the concern of the Industry in receiving more than one (1) Notice of Deficiency (NOD) in a CPR application. We understand that NOD issuance is FDA's assistance to the Industry to avoid outright rejection of CPR applications, however, we hope that FDA can really implement the (1) one time issuance of NOD capturing all minor deficiencies for time efficiency.**

Response:

- To ensure time efficiency, HUHS establishments are requested to ensure that the product registration applications they submit are acceptable to limit the need for NOD issuance. For more information on good quality CPR applications, companies are referred to the HUHS Guide Manual available at https://www.fda.gov.ph/wp-content/uploads/2023/10/Guide-Manual-for-the-HUHS-Industry.pdf. All concerns on the receipt of multiple NODs is duly noted and such cases are continuously reviewed. Rest assured that the concerned team is continuously devising strategies and mechanisms to ensure that all minor deficiencies are captured in a single NOD.

9. Notice of Deficiency (NOD) (2/5)

Question/Comment(s):

- **May we also suggest to retain the Notice of Deficiency (NOD) post transitory period to provide companies a chance to supply the clarification needed in the application instead of an outright disapproval.**

Response:

- The Center is currently reviewing the implementation of the NOD, in consideration of RA 11032, particularly on allowable actions of offices. Updates will be provided in due time.
- Concurrently, the Center has developed multiple initiatives to assist the industry in their compliance to the CPR requirement (ie. release of the HUHS Guide Manual, conduct of workshops, open communication tools, etc.), and intends that such efforts will improve the quality of applications and consequently reduce deficiencies in applications.

9. Notice of Deficiency (NOD) (3/5)

Question/Comment(s):

- **May we propose to revise “calendar” to “working” days to give way to weekends and holidays (especially sudden declarations due to inclement weather or calamities).**

Response:

- The suggestion is noted and will be subject for review since this may be a system limitation, as currently the system is designed to calculate for the compliance period in calendar days. To compensate, the FDA CCHUHSRR set the compliance period to 14 Calendar Days which is more or less the equivalent of 10 Working Days.

9. Notice of Deficiency (NOD) (4/5)

Question/Comment(s):

- **[Minor deficiences...] If this is the only deficiency, propose to release CPR with comments on labels. This will support Sec IV.3.c. "The submission of final artwork of product labels compliant to Annex J of FDA Circular No. 2020-025 shall be a requirement for renewal and shall be subject for review if its label compliance.**

Response:

- CPRs are issued for HUHS product registration applications found to be compliant with existing technical requirements and standards regardless of whether the submitted artwork of the existing product label is compliant with Annex J of FDA Circular No. 2020-025. However, the Center notes that should a proposed label be submitted alongside the other documentary requirements during product registration, this shall be evaluated for compliance with Annex J.
- If minor deficiencies are limited only to non-compliance of submitted existing labels to Annex J of FC 2020-025, the Center issues the CPR with post-approval conditions (found at the back of the CPR), citing the mandatory labeling requirements to be updated or complied with upon CPR renewal.

9. Notice of Deficiency (NOD) (5/5)

Question/Comment(s):

- **Is there an option to request for extension in case the 14 calendar days is not enough to provide the necessary compliance? If one of the days covering the 14 calendar days compliance period falls on a holiday, will the issued 14 days compliance period be adjusted?**

Response:

- Requests for extension of compliance period to answer an NOD may be accommodated in a case-to-case basis, wherein MAH shall provide sufficient justification to warrant such request. Requests may be directed to the HUHS Section of the Center's Licensing and Registration Division at **cchuhsrr.lrd.huhs@fda.gov.ph**.

10. PMS Activities

Question/Comment(s):

- **Since we are in the transitory period (until December 31, 2024), may we request to postpone PMS activities to allow companies to focus on registration and ensuring label compliance.**

Response:

- The FDA would like to clarify that PMS is conducted to ensure safety, efficacy and quality of health products available in the market, hence PMS activities remain to be conducted. Rest assured that regulatory actions pertaining to authorization status will be enforced when the transitory period and other flexibilities have concluded.

11. Full Implementation of FC 2020-025: CPR Requirement (1/2)

Question/Comment(s):

- **If the center issued an approval on a later period of 2024, e.g. last QTR of the year will the center provide additional exhaustion period for the MAH holder to deplete the current/ non-ghs label (e.g. max 6 months) until the GHS compliant label is released on the market?**

Response:

- The FDA is of current view to consider a one-year extension to allow a cumulative 52-month (4 years and 4 months) transitory period by 31 December 2024 for the HUHS registration and labeling requirements. Any further considerations for label exhaustion, in particular, will be subject for further review.

11. Full Implementation of FC 2020-025: CPR Requirement (2/2)

Question/Comment(s):

- **Since FDA has yet to release the Citizen's Charter for HUHS CPR application, may we propose to FDA to give consideration/allowances for HUHS products which a CPR application has been filed but has not yet been acted upon by FDA within a reasonable time before the end of the transitory period extension (1 January 2025).**

Response:

- This request has been duly noted and will be taken into consideration for the decision of the Center management.

12. Full Implementation of FC 2020-025: Promo Permit (1/2)

Question/Comment(s):

- **For the Promo Permit that will be implemented by July 2025, what will be the processing time for the application? How is it applied?**

Response:

- The FDA CCHUHSRR notes that the processing timelines provided in the FDA's Citizen's Charter are aligned with the provisions of RA 11032. It will be no different for the processing of Sales and Promotion Permit with participating HUHS product which the FDA CCHUHSRR intends to be adherent to the processing timelines set in RA 11032.

12. Full Implementation of FC 2020-025: Promo Permit (2/2)

Question/Comment(s):

- **May we clarify if companies are able to start filing promo permit applications during the transitory period if CPRs are already available?**
- **We request for your confirmation if FDA will start accepting promo permit applications during the transitory period.**

Response:

- Referring to Section IV.Guidelines. C. Other Authorizations. 1. Sales and Promo Permits and Custom-related concerns, during the transitory period securing sales and promo permit are not mandatory as the issuance of permits require a valid CPR. The policy includes a proposal to start accepting promo permit applications on 01 June 2025 at the latest.
- For purposes of conducting advertising and sales promotion activities, copies of existing issuances pertaining to the extended transitory period together with a copy of the company's valid FDA-issued LTO as HUHS establishment may be presented to government or non-government entities in lieu of a valid CPR.

13. Collaborative Technical Forums between FDA and Industry

Question/Comment(s):

- **We further propose to have a collaborative technical forums between FDA and Industry for proper resolutions of matter related to implementation of guidelines.**

Response:

- The FDA will be holding activities to discuss HUHS implementation, through Kapihan, technical seminars and stakeholder consultations, wherein we welcome active participation from the HUHS stakeholders.
- The Center will endeavour to increase the frequency of consultations, such as the Kapihan, to improve communication lines between the FDA and the Industry.

14. Labeling (1/2)

Question/Comment(s):

- **May we propose to allow shift of other required labeling information through e-labeling or use of QR code. Rationale behind such proposal is to aid in waste reduction (specifically flexible plastic) as aligned with EPR.**

Response:

- The FDA currently does not accept or allow e-labeling or use of QR code. The FDA CCHUHSRR will consider the inclusion of this concern in the on-going review of current guidelines for HUHS products.

14. Labeling (2/2)

Question/Comment(s):

- **Consideration on the labelling requirements esp for small bottles. It was mentioned that flexibilities will also apply to the current labeling requirements of HUHS Products including products with small bottles – however this is not indicated here – we are looking forward to this specific provision as we are planning on registering products with small bottles. It is not possible that the bottle label does not contain all the minimum labeling requirements as it will not fit in the bottle – because if we try it won't be readable to the consumers as well.**

Response:

- The FDA CCHUHSRR will consider the inclusion of this concern in the on-going review of the current guidelines for HUHS products and may be covered by a separate issuance.

15. Other Authorizations

Question/Comment(s):

- **It would be efficient if the application of promo permits will also be included in the eServices, as well as CFS and GMP renewal/application.**

Response:

- This comment has been duly noted and will be taken into consideration.

END

THANK YOU!

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