FEEDBACK ON THE CONSOLIDATED COMMENTS

Policy Draft for Comments
26 August – 02 September 2022

Proposed issuance "*Updated Guidelines on the Filing and Submission of Applications for the Licensing and Registration of Household/Urban Hazardous Substances (HUHS) Establishments and Products, Respectively, through the FDA E-Portal V.2 System*"

Question / Comment no. 1

May we propose for the User Account to be issued to the Authorized User/Representative/ Qualified Person and not to the Owner, similar to the Center for Foods and Center for Cosmetics. Big companies change their CEO/President (who acts as Owner) after certain years (i.e. 2, 3 years).

- The user registration to secure an e-portal V.2 account for the company MUST be submitted by the owner (i.e., submitted under the owner's name). However, if the concern is that they would not have access to company's registered email (if they registered the owner's email), they may register a company email address instead. It is an internal arrangement within the company how they would ensure they have access to their registered email.
- Applications lodged through the FDA e-Portal V.2. system are a responsibility and accountability of the Owner/President/CEO of an establishment, as such only the duly authorized personnel of applicant-establishments and the e-mail address and its password shall be entrusted with such FDA applications. For purpose of emphasis, all consultants, liaison officers, or freelancers doing business with FDA or work on a per product registration/notification basis shall not be considered as duly authorized or qualified persons.

Question / Comment no. 2

We kindly ask the FDA to reconsider increasing allowable file size per document/total limit and allow other formats such as .jpg for photos and artwork labels. For flexibility, may we request to allow use of either png or pdf in any files.

The allowable file size per document was increased to 4MB per document with total allowable limit of 20MB per application filed. According to the system developers, JPG files have bigger file size than PNG, therefore, would not be ideal to include JPG in the system.

Question / Comment no. 3

Suggest for the system to allow drag and drop feature of files into the system or to allow links to share drive/google drive for files as another option for applications with voluminous submission dossier.

The drag and drop feature of files into the system is unnecessary for the system design as the current feature of uploading files is working. The Center would like to ensure all documents relevant to an application be stored in e-Portal V.2 system. If, for example, shared drives are permitted, there is no guarantee that the documents will be kept accessible to FDA. The drive may become inaccessible to FDA after the application is approved or after the loss of the company's account. Moreover, downloading the documents found in the shared drive would mean that documents relevant to the application will be stored outside e-Portal V.2 which may pose risks on the integrity and security of the files.

Question / Comment no. 4

If we could ask the rationale of less than 40 characters. The number of characters should be aligned with the initially recommended nomenclature.

File names of documents are required to be less than 40 characters in length for easy identification of files.

Question / Comment no. 5

May we propose for FDA to indicate the leadtime for Pre-Assessment for LTO and CPR applications.

Currently, the preliminary assessment conducted by CCHUHSRR covers a review of consistency of information in addition to the review of completeness of submissions against the list of documentary requirements, required under RA 11032. This allows for better screening of applications and feedback given to applicants as a form of assistance during the transitory period.

Question / Comment no. 6

May we clarify the process of applying variations, can the Company proceed to execute with the change/s once the letter has been submitted? For big corporations considering complex structure, may we request for other signatories i.e. Authorized Representative, Qualified Person, Pharmacist, etc.

As stated, all Marketing Authorization Holders whose registered HUHS products have change/s in circumstances are not mandated to apply a variation application during the time that the system is not available. However, they are instructed to submit to the Food and Drug Action Center (FDAC) a signed letter of intent, notifying the Center of said change/s in the product ’s circumstance/s and can proceed the change/s once the letter is submitted. Further, to address the concern on signatories, the letter may also be signed by the company's registered Authorized Representative or Qualified Person, other than the Owner of the company.

Question / Comment no. 7

May we seek further guidance on the number of months required prior expiration date of account renewal must be requested.

The renewal of FDA e-Portal v.2 user accounts shall be made one (1) month before the expiration of the account. Updates in the text of the guidelines will be made to incorporate the said clarification.

Question / Comment no. 8

May we clarify if other Allied Health Profession without PRC Board requirement but with substantial technical experience and training related to the Industry, not qualified to be a Qualified Person?

As per Annex B - Qualified Person (QP) Qualification and Credential Requirements of AO 2020-0017, the qualification/requirements for QP are:

1. PRC ID for Professions with Board/Licensure Exam or Diploma for profession without Board/Licensure Exam, and
2. Certificate of Attendance to seminars, training, learning and development activities on HUHS safety, quality and use

From this, other Allied Health Profession without PRC license can be qualified as QP, provided that a Diploma for the Profession and Certificates of related trainings can be presented.

Question / Comment no. 9

"Results of the tests conducted on the HUHS product as reflected in the COA may also be indicated together with the product specifications."

May we request to ensure and make it clear that this requirement is voluntary and NOT mandatory because it mentioned “may also” which means that it is optional.

Indicating results of test conducted on the HUHS product from the COA may be indicated with the product specification as an option. This requirement is voluntary and NOT mandatory.

Question / Comment no. 10

May we confirm the continued acceptance of Safety Data Sheets based on any GHS version? We learned from the several HUHS Hands on Trainings that different government agencies are currently in discussions on proposed GHS implementation in the Philippines and that the CCHUHSRR plans to adopt their own building blocks coming from this joint issuance. We hope to confirm that SDS following any GHS version will still be accepted while industry awaits the FDA's own implementing guidelines on GHS.

While awaiting update on the JAO for GHS, SDS based on lower versions of GHS are allowed until such time that a definite date for mandatory compliance has been set by FDA. For information, the inter-agency group handling the draft JAO has signified that the Philippines will be adopting the 8th revision of the GHS.

Question / Comment no. 11 (1/2)

May we clarify when and how will the Company submit the proposed artwork since the e-portal system does not have the feature yet for variation applications. In the recent Hands on training, it was mentioned that existing labels regardless of compliance to Annex J will be accepted during CPR application, provided that all claims are substantiated.

- During the transitory period (TP), existing labels regardless of compliance to Annex J will be accepted during CPR application. The TP serves as the exhaustion period for all existing products non-compliant with Annex J, and the time for establishments to create a label that is compliant with Annex J for their products.

- However, it must be noted that the following circumstances shall require the submission of the artwork of the proposed HUHS product label through the FDA e-portal V.2 system upon initial CPR Application:
  a) presence of unsubstantiated product claim/s in the existing label, OR
  b) presence of unallowable safety claim/s in the existing label (In lieu of proposed HUHS product label, a commitment letter stating that the new HUHS product label will no longer reflect the unallowable safety claim may be submitted).

  Submitted proposed HUHS product label shall also be evaluated to determine compliance with Annex J of FDA Circular No. 2020-025 and to verify consistency of information.

Question / Comment no. 11 (2/2)

May we clarify when and how will the Company submit the proposed artwork since the e-portal system does not have the feature yet for variation applications. In the recent Hands on training, it was mentioned that existing labels regardless of compliance to Annex J will be accepted during CPR application, provided that all claims are substantiated.

- If the existing label does not contain any of the above-mentioned circumstances, submission of the proposed artwork is not required, however, the company must ensure the use of new labels compliant to Annex J of FC 2020-025 at the end of TP (Dec 31, 2023).

- Updates in the text of the guidelines will be made to incorporate the mentioned clarifications.

Question / Comment no. 12

Kindly consider including in the system an option to download completed pre-assessment application and disapproval findings in PDF format for record purposes.

The comment has been considered. Please be informed that the system is now updated wherein the results of the pre-assessment and evaluation findings can be viewed in PDF format and can be downloadable/printed from the system.

Question / Comment no. 13

Kindly consider extending NOD compliance period to 14 days as some companies need coordination with Region and Global teams to complete dossier or apply required revisions.

The request to extend the period for NOD Compliance to 14 days is considered. Please note that non-submission of compliance within the provided 14-days submission period will render the application disapproved.

Question / Comment no. 14

May we suggest the compliance to CPR remarks be the expiry or renewal of CPR only since there might be no ample time to comply prior the end of transitory period given actual lead time for preassessment, evaluation, and release of CPR is quite long and that no approved Citizen's Charter has been released for HUHS products.

The compliance period for the post-CPR condition is dependent on the type of compliance found for a certain HUHS product since requirements are time-specific. Hence, depending on findings, compliance will either be at the end of transitory period or renewal of CPR.

Timeline	Requirement
End of Transitory Period	Labeling Requirements GHS Compliance, SDS *(monitored through PMS)*
Renewal of CPR	Stability Studies

END

THANK YOU!

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