FEEDBACK ON THE CONSOLIDATED COMMENTS

Notice and Comments
08-27 September 2023

Proposed issuance *"Guidelines on the Filing and Submission of Applications for the Licensing of Household/Urban Hazardous Substances(HUHS) Establishments through the Food and Drug Administration (FDA) eServices Portal System"*

Question / Comment no. 1

Do we belong to HUHS Distributor if we import finished product and trade it?

Establishments with an activity of importing finished products and the subsequent distribution and/or trade are categorized as distributor-importers.

Distributor- *Any establishment that imports/exports raw materials, active ingredients and/or HUHS products for its own use or for wholesale distribution to other establishments or outlets. If the distributor sell to the general public, it shall be considered a retailer.*

Question / Comment no. 2

For consideration, acceptance of renewal applications with variations, especially for applications that will require inspection to ensure efficient renewal applications. Therefore, may we request for **the removal of line 28-30: "No application for variation of LTO shall be made and granted when an establishment has a pending application for renewal of LTO, or vice versa",** to allow renewal of applications with variations.

The Center appreciates and take note of this recommendation. Currently, due to system limitations, variation and renewal applications must be filed separately, the Center will review and assess system capacities to introduce similar upgrades in the future.

Question / Comment no. 3

For consideration, allowing filing of LTO applications beyond working hours – as companies have different working times and application only involves simple uploading of requirements. Limiting the online system to working hours only is a barrier to companies who want to comply.

The Center echoes the Agency's request for patience and cooperation due to the inconvenience posed by current system limitations. For more information, kindly refer to FDA Advisory No. 2023-0518.

Question / Comment no. 4

We request FDA to explore more payment channels for improved Ease of Doing Business (i.e., credit card).

This recommendation is duly noted. Please be informed that the Agency, through initiatives of the Office of the Director General, is reviewing the incorporation of more payment channels. Updates will be posted through official channels.

Available payment channels based on existing FDA issuances:

- Over-the Counter at the Landbank of the Philippines (LBP) using the LBP Oncoll Payment Slip based on FDA Memorandum Circular No. 2013-046 through this link, *https://bit.ly/36ChH4X*
- Online through:
  - LBP Online Payment Link.Biz Portal based on FDA Advisory No. 2021-0246 (https://bit.ly/3DmdPRv)
  - BANCNET online (https://bit.ly/3uB8PEL)

Question / Comment no. 5

FDA should provide a specific timeline on how long is the process time for transparency

Please be clarified that the processing timelines for HUHS licensing applications is 20 working days, in accordance with Republic Act No. 11032. An extension by the same number of days may take place, provided due notice has been provided to the applicant.

Question / Comment no. 6

May the FDA can reconsider the requirement for Risk Management Plan for Importers, Wholesalers/Distributors. Given that these establishments have significantly lower risk as compared to Manufacturers, the requirement may not be applicable to them.

Please be clarified that risks regardless of scale should be characterized, prevented, or minimized through appropriate interventions, as reflected in respective Risk Management Plans of establishments. We suggest considering a risk-based approach in the development of respective Risk Management Plan by companies, which would allow the elucidation of planned interventions commensurate to identified risks.

Question / Comment no. 7

We recommend FDA to maintain the current list of requirements for LTO applications per AO. No. 2020-0017 Revised Guidelines on Unified Licensing Requirements and Procedures of FDA, Annex A – Requirements for License to Operate to ensure streamlined and simplified government transactions, consistent with R.A. No. 11032 (Ease of Doing Business and Efficient Government Service Delivery Act).

Please be clarified that the requirements as indicated in DOH AO No. 2020-0017 remains to be the same. The enquirer is requested to refer to Annex A of this issuance.

Question / Comment no. 8

Cannot locate http://eservices.fda.gov.ph

We kindly clarify that the module for HUHS licensing will be launched in the FDA eServices Portal System when the consulted Circular calling for its effectivity has been issued.

Question / Comment no. 9

Suggest that the applicant may only file for a renewal application of an LTO within six (6) months prior its expiry. Reason: It will give applicant opportunity to provide data and resubmission time if the application is disapproved. If only 3 months, once the application disapproved and LTO is invalid the business could not be operated

We kindly clarify that this proposed FDA Circular is the procedural guidelines implementing DOH AO No. 2020-0017, wherein Item no. 2.A.4 of its Specific Guidelines under Section VI, explicitly prescribes the 3 month window period for filing renewal applications. The Center kindly suggests that the said recommendation be submitted to pps@fda.gov.ph in connection with the proposed update to the said AO (*https://www.fda.gov.ph/updated-guidelines-on-the-unified-licensing-requirements-and-procedures-of-the-food-and-drug-administration-repealing-administrative-order-no-2020-0017/*)

Food and Drug Administration PHILIPPINES

Question / Comment no. 10

Once payment has been made, LBP or Bancnet will process the payment and send a transaction report to FDA which usually takes a minimum of two (2) – FDA only mentioned the minimum days wherein the transmittal of the report will be generated or issued to FDA , FDA needs to specify as well the maximum days to which the report will be issued to them and a definite time on how long it will take FDA to post the payment on the e-service to update the status of payment. Concern is that cash or cheque payment made to FDA via landbank on-call slip or landbank e-bizz, it takes them 1 week up to a month to update the payment via e-portal. Will the new system be faster in updating/ posting?

This concern is duly-noted and is currently being reviewed by the Agency through its Cashier Section. Further, please be informed that the Agency, through initiatives of the Office of the Director General, is reviewing the incorporation of more payment channels. Updates will be posted through official channels.

Question / Comment no. 11 (1/2)

We suggest for FDA to take risk-based approach on assessing need and limit pre-licensing inspection to **1.** Initial LTO application as Manufacturers or **2.** Major Variations requiring significant changes and not "all FDA-covered establishments" - as these present significant risk as compared to other establishments such as distributors or importers which distribute already finished products in market.

We propose that:

a. Pre-inspection for Initial LTO application for Manufacturers and/or Major Variations as specified in Annex A, Section C. Variation Application of this draft guideline, however, subject to risk-based approach to determine the need for pre-inspection.

b. Post-licensing inspection for Initial LTO application for Distributors/Wholesalers, Importers and Traders.

The conduct of pre-licensing inspection to all FDA-covered establishments may pose a challenge and can be a source of delay for business operations. In this case, it will not be consistent with the objective of R.A. No. 11032 (Ease of Doing Business and Efficient Government Service Delivery Act).

Question / Comment no. 11 (2/2)

Please be clarified that this proposed FDA Circular will follow the existing licensing policy under DOH AO No. 2020-0017 including its future amendments. We take note of the concern posed by the enquirer, and confirm that risk-based approaches are applied in the determination of the need and frequency of inspections.

For the concern pertaining to possible delays in business operations due to the proposed reinstatement of pre-licensing inspections in the on-going initiative to update of DOH AO No. 2020-0017, please be informed that the appropriate reviews are being made by the concerned offices of the Agency, including its inspectorate, to consider its capacity to timely conduct inspections.

Question / Comment no. 12 (1/2)

We recommend this section to read as “Repacker – refers to any establishment that repacks a finished product into smaller quantities in a separate container and/or secondary packaging, including but not limited to relabeling with the end view of storage, distribution, or sale of the product.”

We propose to remove stickering and bundling for promo packs as a Repacker activity given these are minor activities that do not impact product quality, safety or efficacy of the product.

Additionally, stickering and bundling activities done at point-of-sale is outside the scope and definition of a ‘Repacker’ to reflect the fact that such minor activities not impacting product quality, safety, and integrity can be done at point-of-sale as part of store promotions and does NOT require LTO as Repacker

Question / Comment no. 12 (2/2)

The Center posits that quality and safety are affected by changes made to packaging and labeling, we disagree with the position made by the enquirer and retain that the highlighted activities remain within the definition of Re-packer.

Packaging and re-packaging are part of the process of producing a finished product, such activities must be performed consistent with Good Manufacturing Practices. Further, it is important to emphasize that labels are the primary means to communicate safety and quality information to the consumer, such that it is required that labels must bear minimum information to communicate a product's identity and proper use, and that such shall not be deceptive or misleading. Stickering and bundling introduce elements that may obscure or add information that alters product presentation to the user, and thusly may affect product perception/appreciation on identity and appropriate use consequently affecting safety and quality.

The Center however further clarifies that it has applied considerations for distributors, wherein they may be allowed to perform bundling and stickering of their duly-notified products to bring into conformity to regulations normally under the activity of licensed Re-packers, subject to review and approval.

Question / Comment no. 13

Suggestion that the FDA may release a one pager memo/circular to announce the change of submission portal from e-Portal v.2 to e-Services with a user manual. Instead of issuing a new circular with few to no change the current guideline except for the system

The Center takes note of and appreciates the recommendation of the enquirer. However, we kindly clarify that the issuance intends to provide consolidated guidelines on the most current system and procedure, for all establishments intending to apply either a NEW, RENEWAL, or VARIATION application.

Question / Comment no. 14

Other comments:

- Requesting for the extension of transitory period for another 2 years.
- Multiple rejection on sending the application
- Requesting for the face to face requirements submission or FDA can provide for a consultation that can discuss the correct or proper paperwork.

The Center takes note of this concern which we understand is made in relation to the HUHS registration requirements under FDA Circular No. 2020-025. Please be informed that FDA Circular No. 2021-011-A is currently being reviewed, updates shall be announced through official channels in due course.

THANK YOU!

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