

ANNEX A

Procedures of Releasing Food and Drug Administration (FDA) Authorizations at Records Section-Releasing Unit (RS-RU)

Notification Phase:

Upon approval, the Releasing Unit will initiate the notification process.

Clients will receive a detailed email alert containing the following information:

- a. Company Name and/or Document Tracking Number (DTN), as applicable.
- b. Type of Application/Authorization that is ready for pick-up.

The email will serve as an official notification that their FDA authorizations are available for pick-up at the RS-RU. This additional information ensures that clients are well-informed about the specifics of their authorized documents, making the pick-up process smoother and more organized.

Documentation Verification:

1. Clients are required to present the received email confirmation, indicating that their FDA authorizations are ready for pick-up.
2. The confirmation email should include details such as Company Name, Document Tracking Number (DTN), and the Type of Application/Authorization.
3. If the client is not the owner of the company:
 - A valid authorization letter from the owner of the company is mandatory.
 - The authorization letter should preferably be written on the company letterhead and include the company logo.
 - Clients are required to provide photocopies of the following identification documents:
 - Photo copy of the owner's valid ID.
 - Photo copy of the ID of the authorized representative.

These additional requirements ensure the security and accuracy of the authorization release process, particularly in cases where the client is not the owner of the company.

Acknowledgment and Signature:

- Upon successful verification, the Releasing Staff shall provide the client with a receiving copy of the authorization.
- The receiving copy will be presented for the signature of the Company Representative.
- The Company Representative shall sign the receiving copy as an acknowledgment of the

- receipt of the authorization.
- Subsequently, the Releasing Staff shall issue the original copy of the authorization to the signed representative of the company.

This formal signing process ensures a documented acknowledgment of the receipt by the company representative and facilitates a clear trail of the authorization handover process.

Adherence to Guidelines in Annex A:

Clients and Releasing Unit personnel are expected to adhere to the guidelines outlined in Annex A of the Advisory document for a smooth and standardized releasing process.

This set of procedures aims to ensure a transparent, efficient, and client-friendly process for the release of FDA authorizations at RS-RU.