

Recent Questions/Requests By FDA

- Identify the contact(s) at the firm who are authorized to discuss product removal from the market as well as public notification of the cargo theft.
- What has the firm determined about the theft?

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- Provide a list of all products that were stolen to include (but not limited to):
 - Finished product (prescription, OTC), samples, bulk product, API etc.
 - Description of product stolen (capsules, injectables etc.)
 - Quantity of each product stolen
 - Description of packaging/containers
 - Lot number(s) and NDC number(s)
 - Storage/handling requirements for the product(s)
 - Tampering protections in packaging

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- Were the entire lots stolen; had a portion of the stolen lot(s) been legitimately distributed prior to the theft?
- Quantity of related lots of product in legitimate distribution and/or secured?
- Have any controls been put into place since the theft to stop distribution of other products from the affected lots - or similar products?
- What has the firm determined is the risk posed by the products that were stolen, e.g., the firm's risk assessment ?

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- Does the firm intend to inform/warn the public about the products that were stolen? If so, how and when? If the firm intends to issue a Press Release, is the firm willing to share the Press Release with FDA for input prior to issuance ?
- Has the firm already sent any communication(s) to customers about the stolen products?

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- Has/will the firm develop an Action Plan in response to this theft? Will the firm share the Action Plan with FDA - When?
- What steps should consumers take who receive the stolen product? Discontinue use, return product (where?), call firm?
- Does the firm have any information regarding where this product will be sold/distributed?