Medytox

Medytox
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Falsified Siax 200 Units Identified in Saudi Arabia – Not Associated with Authorized Product

Dear Healthcare Professional,

Medytox would like to inform you of the following:

Medytox in agreement with Saudi Food and Drug Authority (SFDA) would like to inform you of a critical safety concern related to falsified Siax 200 Units (Botulinum Toxin Type A), recently identified in the Kingdom of Saudi Arabia. These counterfeit products were not manufactured, released, or distributed by our company and differ significantly from the approved product.

Summary

The following discrepancies have been observed in the falsified products.

- **Siax 200 Units (Registration number [3-606-20]) was manufactured under strict Good Manufacturing Practice (GMP) conditions, but counterfeit product were not manufactured under regulated conditions, which may pose significant health risks.**
- **Labeling Irregularities were found in the counterfeit labels (including the counterfeit labels do not match the approved labeling as authorized by the Saudi Food and Drug Authority (SFDA)).**
- **Notable inconsistencies include use of incorrect font type, type errors, spacing errors, and overall poor printing quality were identified in the counterfeit labels.**
- **There is no Cap Printing on the side of aluminum vial cap.**

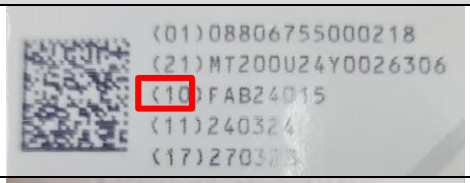
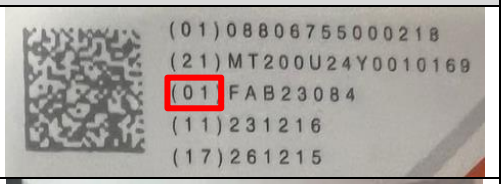
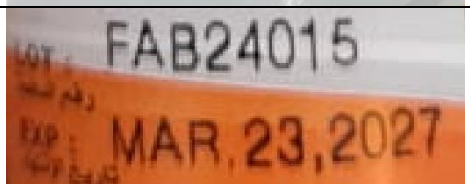
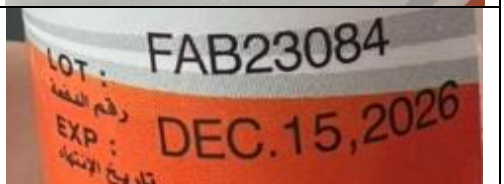
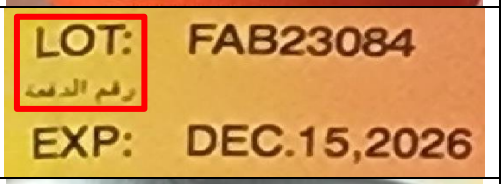
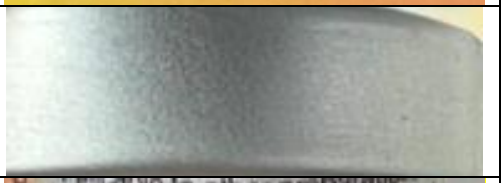
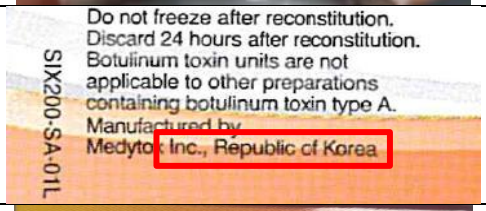
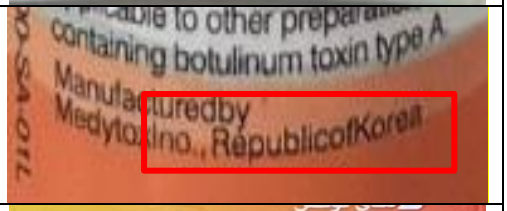
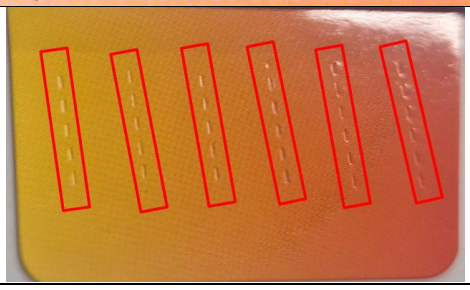
Background

We confirm that the falsified product is not associated with our manufacturing facilities or authorized distribution network. The integrity of our products remains intact, and no deviation has been identified in our legitimate supply chain.

Siax 200 Units approved under Registration number [3-606-20], was manufactured under strict Good Manufacturing Practice (GMP) conditions, ensuring quality, safety, and efficacy for all patients.

As these products were not manufactured under regulated conditions, they may pose significant health risks including unexpected adverse reactions or therapeutic failure.

Please see below table for differences between Medytox Siax and Counterfeit product.

Different Point	Medytox Siax	Counterfeit Siax
1. Font 2. Error in (10) 3. Letter spacing		
1. Font 2. Letter spacing 3. Label printing	 	 
1. Print missing		
1. Missing of space 2. Typo		
1. Cut lines missing on the carton		

Comments	1. Serial Number System: The counterfeit products appear to replicate identical serial numbers issued by the manufacturer. The font and spacing of the serial numbers are consistent across multiple units, indicating duplication. Additionally, the manufacturing code is incorrectly printed as (01) instead of the correct (10). 2. Printing Details: The LOT and EXP information printed on the vial labels of counterfeit units are suspected to be manually applied rather than printed by authorized equipment. Similarly, the LOT and EXP details on the carton and labels have uniform font and spacing, which is atypical of genuine products. Moreover, the manufacturing number is missing on the cap of the counterfeit vial. 3. Carton: The counterfeit carton lacks the perforated cut line that facilitates adhesion. This cut line area normally has adhesive applied on the inside to enhance carton sealing, but this feature is missing in the counterfeit carton. 4. Aluminum vial cap: The aluminum vial cap of the counterfeit product is unprinted, whereas all genuine vials intended for the Saudi market include distinct printed markings on the cap in accordance with approved specifications.

Advice for healthcare providers

- Visually inspect product packaging and labeling prior to administration. Pay close attention to vial cap printing and labeling font.
- Verify batch numbers and product integrity using official channels.

Yours faithfully,

Medytox Inc.
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