

ALERT- UNREGISTERED OXYTOCIN ON THE GHANAIAN MARKET

FDA/CSD/CPE/PRS/23/011

21st April 2023

During its routine market surveillance activities, the Food and Drugs Authority (FDA) has detected the presence of unregistered **OXYTOCIN INJECTION 10iu/ml** in some health facilities, including pharmacies in the country. Details of the unregistered products are as follows:

Product name	Manufacturer	Country of Origin	Batch Nos.
Beltocin	Belco Pharma PVT Ltd	India	All batches (with storage conditions 15°C - 30°C)
Oxytocin	Entrance Pharmaceuticals	Ghana	All batches
Oxytocin	AMROS Pharma	Pakistan	All batches
Oxytocin	Anhui Hongye Pharmaceutical Company Ltd.	China	All batches
Oxytocin	Jackson Laboratories PVT Ltd	India	All batches
Oxytocin	Jiangsu Ruinian Quianjin Pharmaceutical Company Ltd.	China	All batches
A-tocin	Health Care Pharma	N/A	All batches

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Product name	Manufacturer	Country of Origin	Batch Nos.
Extocin	Anhui Hongye Pharmaceutical Company Ltd.	China	All batches
Pitons	Shanxi Shuguang Pharm. Company Ltd.	China	All batches
Gold Vision	Anhui Hongye Pharmaceutical Company Ltd	China	All batches
Derm	Shandong Shenglu Pharmaceutical Company Ltd.	China	All batches

To protect public health and safety, the FDA has initiated a recall of all batches of the above products. The public is to note that because these products are not registered, their quality, safety and efficacy cannot be ascertained by the Authority. Consequently, the use of these unregistered products could be associated with life-threatening or serious risks to health.

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In view of the above, healthcare professionals are advised to stop supplying all batches of any of these products immediately and any in stock should be quarantined or returned to the nearest FDA office for safe disposal.

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Meanwhile, the FDA is liaising with security and intelligence agencies to apprehend the importers to ensure that the market is rid of these unregistered pharmaceutical products.

The Authority is taking the necessary regulatory actions to prevent any future occurrence and will not hesitate to apply the strictest sanctions, including criminal prosecution (with a jail term up to 15 years) and the imposition of administrative fines.

The FDA assures the public of the integrity of its regulatory processes which ensure that medical and other regulated products registered for use on the Ghanaian market are safe, efficacious and of the right quality.

The public is once again reminded to check the registration status of all regulated products from the FDA website: www.fdaghana.gov.gh and on the ProPer Platform (https://bit.ly/ProPerFDA_Verify) before purchase in order to avoid any harm.

For further information, please contact the FDA on any of the contacts below:

Signed

Chief Executive Officer
Food and Drugs Authority

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