

RAPID ALERT NOTIFICATION OF A QUALITY DEFECT/RECALL
IMPORTANT – DELIVER IMMEDIATELY

		Reference Number
[add letter head of sender]		
1. To: (see list attached, if more than one)		
2. Product Recall Class of Defect: I II (circle one) Not yet classified, potential class	3. Falsification / Fraud (specify)* N/A	
4. Product: dietary supplement	5. Marketing Authorisation Number: * For use in humans	
6. Brand/Trade Name: Shogun-X 7000, Thumbs Up 7 (Black) 25K, Thumbs Up 7 (White) 11K, 69MODE Blue 69	7. INN or Generic Name: unknown	
8. Dosage Form: capsules	9. Strength: N/A	
10. Batch number (and bulk, if different): All lots and all presentations	11. Expiry Date: all lots within expiry	
12. Pack size and Presentation: 1-count capsule in blister card and 10-count capsule boxes	13. Date Manufactured: *	
14. Marketing Authorisation Holder*: N/A		
15. 1 Manufacturer: unknown Contact Person: Telephone:	16. Recalling Firm (if different): Nuri Trading LLC Contact Person: Telephone: 201-380-2836	
15.2 Where the defect is attributed to a manufacturing site, site where defect occurred (if different from 15.1): Contact Person: Telephone:		
17. Recall Number Assigned (if available): RES 87624		
18. Details of Defect/Reason for Recall: Due to the Presence of Undeclared Sildenafil, Tadalafil and/or vardenafil		
19. Information on distribution including exports (type of customer, e.g. hospitals): *		
20. Action taken by Issuing Authority: The firm issued a US nationwide press on 3/29/2021 and updated this press on 6/22/2021		
21. Proposed Action: U.S. Food and Drug Administration is monitoring this recall.		

22. From (Issuing Authority): U.S. Food and Drug Administration		23. Contact Person: Telephone:
24. Signed:	25. Date:	26. Time: *

* Information not required, when notified from outside EU.

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