

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: Arize Herbal Dietary Supplement Capsules		5. Marketing Authorisation Number: * For use in humans
6. Brand/Trade Name: Arize Herbal Dietary Supplement Capsules		7. INN or Generic Name:
8. Dosage Form: Capsule		9. Strength: N/A
10. Batch number (and bulk, if different): 2107, EXP: 10/2024		11. Expiry Date: 10/2024
12. Pack size and Presentation: 10 capsules		13. Date Manufactured: * N/A
14. Marketing Authorisation Holder*: N/A		
15. 1 Manufacturer: Contact Person: Telephone:		16. Recalling Firm (if different): Today the World Telephone:
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): TBD		
18. Details of Defect/Reason for Recall: Marketed without an Approved NDA/ANDA. Product is being recalled due to the Presence of Undeclared Nortadalafil		
19. Information on distribution including exports (type of customer, e.g. hospitals): The product was distributed via website www.getarize.com in the USA.		
20. Action taken by Issuing Authority: Firm issued press on 02/02/2024 and it was posted on FDA website on 02/05/2024. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/today-world-issues-voluntary-nationwide-recall-all-lots-arize-herbal-dietary-supplement-capsules-due		
21. Proposed Action: U.S. Food and Drug Administration is monitoring this recall.		

UB Держпродспоживслужба
 № 13/3165/24
 02.02.2024

38

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22. From (Issuing Authority): U.S. Food and Drug Administration		23. Contact Person: Telephone: 301-796-3130	
24. Signed: Shiva Shahabadi - <small>Digitally signed by Shiva Shahabadi 5 Date: 2024.02.21 16:53:34 +0500</small>	25. Date:	26. Time: *	

* Information not required, when notified from outside EU.

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