

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: (circle one) Not yet classified, potential class	(I) II	3. Falsification / Fraud (specify) *
4. Product: 1) UP2 2) Bow and Arrow	5. Marketing Authorisation Number: * For use in humans	
6. Brand/Trade Name: 1) UP2 2) Bow and Arrow	7. INN or Generic Name: N/A	
8. Dosage Form: Capsules	9. Strength: N/A	
10. Batch number (and bulk, if different): Lot: 030419 (UP2); 0217 (Bow and Arrow)	11. Expiry Date: N/A	
12. Pack size and Presentation: 1 count, 4 count and 10 count blister foil packaging	13. Date Manufactured: *	
14. Marketing Authorisation Holder*: N/A		
15.1 Manufacturer†: Contact Person: Telephone:	16. Recalling Firm (if different): Med Man Pickrel River, Ontario Canada Contact Person: Derek Lepage, Owner Telephone: 705-297-5321	
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: FDA analysis found the products to contain undeclared sildenafil.		
19. Information on distribution including exports (type of customer, e.g. hospitals): US		
20. Action taken by Issuing Authority: Firm issued a press release on November 8, 2019 and sent another press release on February 21, 2020 expanding the recall. The firm also sent recall letters to customers on November 12, 2019 and on February 21, 2020 expanding the recall.		
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: Silvia Wanis Telephone: 301-796-3130
24. Signed:	25. Date: 3/9/2020	26. Time: *

* Information not required, when notified from outside EU.

This is intended only for the use of the party to whom it is addressed and may contain information that is privileged, confidential, and protected from disclosure under applicable law. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please notify us by telephone immediately and return it to us at the above address by mail. Thank you
