IMPORTANT – DELIVER IMMEDIATELY
Rapid Alert Notification of a Quality Defect / Recall

		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 probable class I (I) II		3. Falsification / Fraud (specify)
4. Product: Super Panther 7K Capsules, Distributed by SX Power Co, Brooklyn, NY	5. Marketing Authorisation Number: For use in humans	
6. Brand/Trade Name: Super Panther 7K Capsules	7. INN or Generic Name:	
8. Dosage Form: Capsules	9. Strength:	
10. Batch number (and bulk, if different): • Lot RO246852, Exp 8/28/2020 (6-count bottles UPC 6 01577 51320 9), • Lot RO846356, Exp 08/28/2020 1-count hanging cards UPC 6 015577 51324 7 in a box of 30	11. Expiry Date:	
12. Pack size and Presentation: 6 count bottles, 1 count hanging cards.	13. Date Manufactured:	
14. Marketing Authorisation Holder: N/A		
15. Manufacturer†: Happy Together, Inc. Contact Person: Telephone:	16. Recalling Firm (if different): Chiavna Saffron LLC Contact Person: Khowaja Omar, Member Manager Telephone: 704-579-5726	
17. Recall Number Assigned (if available): NA		
18. Details of Defect/Reason for Recall: Marketed without an Approved NDA/ANDA; FDA analysis found product to contain sildenafil and tadalafil		
19. Information on distribution including exports (type of customer, e.g. hospitals): US		
20. Action taken by Issuing Authority: Firm issued public notification on July 22, 2017 and emailed recall letters between July 20 and 28, 2017.		
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: 301-796-3202
24. Signed: Lavonia Huff	25. Date: 7/31/2017	26. Time:

* Information not required, when notified from outside EU.

† The holder of an authorisation referred to under Article 40 of Directive 2001/83/EC or Article 44 of Directive 2001/82/EC and the holder of the authorisation on behalf of whom the Qualified Person has certified the batch for release in accordance with Article 51 of Directive 2001/83/EC or Article 55 of Directive 2001/82/EC if different.

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