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

		Reference	Number	
[add letter head of sender]				
class		3. Falsificati	on / Fraud (specify)	
	5. Marketing Authorisation Number: For use in humans			
	7. INN or Generic Name: N/A			
	9. Strength: N/A			
t): all	11. Expiry Date: all lots			
, UPC	13. Date Manufactured: unknown			
14. Marketing Authorisation Holder: N/A				
	16. Recalling Firm (if different): AMPT Life, LLC			
	Contact Person: Customer Service			
	Telephone: 214-838-7544			
17. Recall Number Assigned (if available): not yet classified				
18. Details of Defect/Reason for Recall: Marketed Without An Approved NDA/ANDA: FDA laboratory analysis found the product to contain undeclared sildenafil, tadalafil, and milk				
19. Information on distribution including exports (type of customer, e.g. hospitals): Distributed nationwide in the USA via internet sales.				
20. Action taken by Issuing Authority: firm issued a press release on 08/01/17 <a href="https://www.fda.gov/safety/recalls/ucm569558.htm">https://www.fda.gov/safety/recalls/ucm569558.htm</a>				
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: Doris Chin Telephone: 301-796-3130	
25. Da	ate: 08/02/17		26. Time:	
	i): all  , UPC  A  Market ndeclare g expor irm issu n56955i ig Admi	5. Marketing A For use in hur 7. INN or Gen 9. Strength: N 11. Expiry Da 11. Expiry Da 12. Date Manu 13. Date Manu 14. Contact Perso Telephone: 21 15. Telephone: 21 16. Recalling II 17. Contact Perso Telephone: 21 18. Telephone: 21 19. Telephone:	5. Marketing Authorisation For use in humans 7. INN or Generic Name: N 9. Strength: N/A 11. Expiry Date: all lots 13. Date Manufactured: ur 16. Recalling Firm (if differ Contact Person: Customer Telephone: 214-838-7544 2): not yet classified  Marketed Without An Approved ND indeclared sildenafil, tadalafil, and may exports (type of customer, e.g. hos.  irm issued a press release on 08/01/1569558.htm  ug Administration is monitoring this 23. Contact Telephone	

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<sup>\*</sup> Information not required, when notified from outside EU.

<sup>†</sup> 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.