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

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|---|---|---|
| | | **Reference Number** |
| [add letter head of sender] | | |
| 1. To:<br>(see list attached, if more than one) | | |
| 2. Product Recall Class of Defect:<br>(circle one) Not yet classified, potential class (I) II | | 3. Falsification / Fraud (specify) |
| 4. Product: Natural Herbal Coffee | 5. Marketing Authorisation Number:<br>For use in humans | |
| 6. Brand/Trade Name: AMPT | 7. INN or Generic Name: N/A | |
| 8. Dosage Form: coffee packets | 9. Strength: N/A | |
| 10. Batch number (and bulk, if different): all lots | 11. Expiry Date: all lots | |
| 12. Pack size and Presentation: Carton containing red packets of instant coffee, UPC 6942630912 | 13. Date Manufactured: unknown | |
| 14. Marketing Authorisation Holder: N/A | | |
| 15. Manufacturer†:<br><br>Contact Person:<br><br>Telephone: | 16. Recalling Firm (if different): AMPT Life, LLC<br><br>Contact Person: Customer Service<br><br>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<br>https://www.fda.gov/safety/recalls/ucm569558.htm | | |
| 21. Proposed Action: U.S. Food and Drug Administration is monitoring this recall. | | |
| 22. From (Issuing Authority):<br>U.S. Food and Drug Administration | | 23. Contact Person: Doris Chin<br><br>Telephone: 301-796-3130 |
| 24. Signed: Doris Chin -S<br>Digitally signed by Doris Chin -S<br>DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Doris Chin -S, 0.9.2342.19200300.100.1.1=2000350372<br>Date: 2017.08.02 07:35:02 -04'00' | 25. Date: 08/02/17 | 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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