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: Vy&Tea	5. Marketing Authorisation Number: * For use in humans	
6. Brand/Trade Name: Vy&Tea	7. INN or Generic Name:	
8. Dosage Form: sachets	9. Strength	
10. Batch number (and bulk, if different): all lots distributed between October 2020 to March 2021".	11. Expiry Date: Best By Date 09/2021	
12. Pack size and Presentation: . 1) Box contains 15 sachets 2) Box contains 45 sachets	13. Date Manufactured:	
14. Marketing Authorisation Holder*: N/A		
15.1 Manufacturer†: Contact Person: Telephone: 15.2 Where the defect is attributed to a manufacturing site, site where defect occurred (if different from 15.1): Contact Person: Telephone:	16. Recalling Firm (if different): Daisy Fate's Teas Qikmoov, LLC – Vyteasus.com 14831 Piuma Ave Norwalk, CA 90650 Contact Person: Ms. Trinh Nguyen Telephone: contact@vyteaus.com	
17. Recall Number Assigned (if available):		
18. Details of Defect/Reason for Recall: FDA laboratory analysis confirmed that Vy & Tea contains sibutramine. Sibutramine is a controlled substance that was removed from the market in October 2010 for safety reasons. FDA issued an alert on 2-26-2021 and updated it on 7-16-2021 https://www.fda.gov/drugs/medication-health-fraud/public-notification-vy-tea-contains-hidden-drug-ingredient		
19. Information on distribution including exports (type of customer, e.g. hospitals): Distribution Nationwide in the USA via the internet and to the following countries Brazil, Canada, Germany, France, Hong Kong, Italy, Sweden, Switzerland, Thailand, and United Kingdom.		
20. Action taken by Issuing Authority: On 7/14/21, the recalling firm sent emails to customers to notify them of 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: Simonne Quiros Telephone: 301-796-3130
24. Signed: Simonne Quiros -S Digitally signed by Simonne Quiros -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Simonne Quiros -S, 0.9.2342.19200300.100.1.1=2000558240 Date: 2021.08.02 08:34:13 -04'00'	25. Date: 8/2/2021	26. Time: *

* Information to be filled in when notified from outside EU.

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