

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		3. Falsification / Fraud (specify) *
4. Product: The Silver Bullet 10x Capsules, 10 count mylar packaging, Nature's Rx, Claremont, CA 91711		5. Marketing Authorisation Number: * For use in humans
6. Brand/Trade Name: the Silver Bullet		7. INN or Generic Name: proprietary blend of: Mucuna Pruriens Extract, Horny Goat Weed, Ginger Root Extract, Icariin, Wolf Berry (fruit) Lactase, Tribulus Terrestris Extract, Piperine.
8. Dosage Form: Capsule		9. Strength: 725 mg
10. Batch number (and bulk, if different):		11. Expiry Date: 11/2020
12. Pack size and Presentation: 10 count mylar packaging		13. Date Manufactured: *
14. Marketing Authorisation Holder*: N/A		
15.1 Manufacturer†: Contact Person:		16. Recalling Firm (if different): Nature's Rx, Claremont, CA Contact Person: Alek Bhairi, Owner Telephone: 310-961-1494
Telephone:		
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 product to contain undeclared sildenafil and tadalafil		
19. Information on distribution including exports (type of customer, e.g. hospitals): US		
20. Action taken by Issuing Authority: Firm began sending emails to customers on January 25, 2019 and press was issued January 29, 2019. https://www.fda.gov/Safety/Recalls/ucm630104.htm		
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: 301-796-3130
24. Signed:	25. Date:	26. Time: *

* Information not required, when notified from outside EU.

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