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: (I) II (circle one) Not yet classified, potential class	3. Falsification / Fraud (specify)*
4. Product: ADVANCED GLUCOSE SUPPORT Dietary Supplement Capsules	5. Marketing Authorisation Number: * For use in humans
6. Brand/Trade Name: Dr. Ergin's SugarMD, ADVANCED GLUCOSE SUPPORT	7. INN or Generic Name:
8. Dosage Form: N/A	9. Strength: N/A
10. Batch number (and bulk, if different): LOT#22165-003	11. Expiry Date: N/A
12. Pack size and Presentation: 60,120 & 180-count bottles	13. Date Manufactured: N/A
14. Marketing Authorisation Holder*: N/A	
15.	16. Recalling Firm (if different): SUGARMDS LLC 11470 Schenk Dr Maryland Heights, MO, 63043-3417
15.2 Where the defect is attributed to a manufacturing site, site where defect occurred (if different from 15.1):	
17. Recall Number Assigned (if available): RES 93394	
18. Details of Defect/Reason for Recall: Marketed Without an Approved NDA/ANDA- FDA analysis has found the product to be tainted with glyburide and metformin.	
19. Information on distribution including exports (type of customer, e.g., hospitals): Nationwide and online websites.	
20. Action taken by Issuing Authority: FDA issued a Consumer Health Warning on its website (11.3.2023). Firm issued press (11.8.2023) Recall was initiated on 11.13.2023.	
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: 301-796-3323
24. Signed: C. Howard	25. Date: 11/28/2023	26. Time: 0900

* Information not required, when notified from outside EU.

REPUBLIC OF BULGARIA
MINISTRY OF AGRICULTURE AND FOOD
BULGARIAN FOOD SAFETY AGENCY

IMPORTANT DELIVER IMMEDIATELY

Rapid Alert Notification of a Quality Defect / Recall

	Reference Number : Quality Defect Alert BG/I/02/23

QUALITY DEFECT RAPID ALERT	
1. To: Quality defect rapid alert contacts(see list attached, if more than one)	
2. Product Recall Class of Defect: (circle one): **TYPE I**	3. Counterfeit / Fraud (specify)*
4. Product: **Veterinary Medicinal Products**	5. Marketing Authorisation Numbers: 0022-1649 For use in animals
6. Brand/Trade Name: **OXYTETRACYCLIN hydrochloride-NGP 22/ 1,020 g comprettae spumescentes**	7. INN or Generic Name:
8. Dosage Form: **intrauterine tablet**	9. Strength:
10. Batch number (and bulk, if different): **22-010123**	11. Expiry Date: 01/2025
14. Marketing Authorisation Holder: **NGP Pharm EOOD** 10 Hadji Angel Str., 5400, Sevlievo, Republic of Bulgaria Contact person:	
15. Manufacturer: **SEVEREN VETERINAREN DILAR-SVD" OOD,** 10 Hadji Angel Str., 5400, Sevlievo, Republic of Bulgaria	16. Recalling Firm (if different):
18. Details of Defect/Reason for Recall: After routine sampling major inconsistencies have been identified relating to the text on the batch product labelling (e.g. withdrawal period and target species).	
20. Action taken by Issuing Authority: **Order for recall of the affected batch to vet. level.**	
21. Proposed Action: **No batch distribution outside of Bulgaria.**	
22. From (Issuing Authority): BULGARIAN FOOD SAFETY AGENCY	23. Contact Person: **Miroslav Georgiev** **Telephone:** **Email: mg_georgiev@bfsa.bg**

24. Signed:	25. Date: 29 November 2023	26. Time: *

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: (I) II (circle one) Not yet classified, potential class	3. Falsification / Fraud (specify)*
4. Product: Dietary supplements	5. Marketing Authorisation Number: * For use in humans
6. Brand/Trade Name: Kuka Flex Forte, Reumo Flex (caplets), and Artri King (tablets)	7. INN or Generic Name: N/A
8. Dosage Form: Caplets and Tablets	9. Strength: N/A
10. Batch number (and bulk, if different): All batches	11. Expiry Date: all
12. Pack size and Presentation: Artri king in the bottles with 100 tablets. Kuka Flex in the bottles with 30 caplets. Reumo flex in the boxes with 30 caplets.	13. Date Manufactured: *
14. Marketing Authorisation Holder*: N/A	
15. 1 Manufacturer: Contact Person: Telephone:	16. Recalling Firm (if different): Botanical-Be Telephone: (915) 412-6237 or by e-mail at botanical.be@gmail.com
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): 93257	
18. Details of Defect/Reason for Recall: Due to the Presence of Undeclared Diclofenac.	
19. Information on distribution including exports (type of customer, e.g. hospitals): These products were distributed nationwide via the internet.	
20. Action taken by Issuing Authority: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/botanical-be-issues-voluntary-nationwide-recall-kuka-flex-forte-reumo-flex-caplets-and-artri-king#:~:text=of%20Undeclared%20Diclofenac-,Botanical%2DBe%20Issues%20Voluntary%20Nationwide%20Recall%20of%20Kuka%20Flex%20Forte,announcement%20as%20a%20public%20service.	
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: Beatriz Caceres-gentile -S Digitally signed by Beatriz Caceres-gentile -S Date: 2023.11.28 09:25:57 -05'00'	25. Date:	26. Time: *

* Information not required, when notified from outside EU.