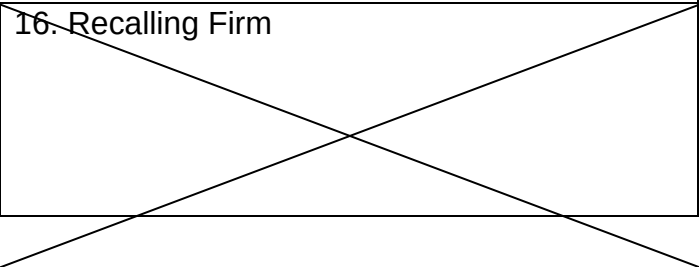


RAN-Formular (Rapid-Alert-Notification) zur Mitteilung über den RAS-Verteiler

DRINGEND - BITTE SOFORT AUSLIEFERN! IMPORTANT - DELIVER IMMEDIATELY		
Rapid Alert Notification of a Medicinal Product Falsification		
☒ ASSUMED ☐ REASONABLY SUSPECTED ☐ VERIFIED		
Regierungspräsidium Karlsruhe Referat 25 – Ärztliche und Pharmazeutische Angelegenheiten Markgrafenstr. 46 76133 Karlsruhe		
1. To / Empfänger:		FAX
☒	Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)	0228-207-4636
☐	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)	030-18444-30409
☐	Paul-Ehrlich-Institut / Bundesamt für Sera und Impfstoffe - (PEI)	06103-77-1263
☒	Ministerium für Soziales und Integration Baden-Württemberg, Referat 53, Else-Josenhans-Str. 6, 70173 Stuttgart	0711-123-3816
2. Classification (not mandatory)		3. Falsification
4. Product: Cockfosters TM 100		5. Marketing Authorisation Number: * GUJ/DRUGS-G/25/1325 For use in humans/ (delete as required)
6. Brand/Trade Name: Cockfosters TM 100		7. INN or Generic Name:
8. Dosage Form: Tablets		9. Strength: 100 mg Sildenafil
10. Batch number (and bulk, if different): TC-080001		11. Expiry Date: 02/2022
12. Pack size and Presentation: 10X10 tablets		13. Date Manufactured: 03/20219
14. Marketing Authorisation Holder: * Shree Venkatesh (India)		
15. Manufacturer†: Contact Person: Telephone:		16. Recalling Firm 

17. Rapid Alert Notification Reference Number: DE_		
18. Details:		
19. Information on distribution including exports (e.g. type of customer, e.g. hospitals): * Suspicion of the distribution of drugs through illegal distribution channels DB Consult s.r.o Klincova 35 82108 Bratislava 3 Slovakia		
20. Action taken by Issuing Authority: FOR YOUR INFORMATION The goods were secured by the customs office		
21. Proposed Action:		
22. From (Issuing Authority): Regierungspräsidium Karlsruhe mail to: abteilung2@rpk.bwl.de	23. Contact Person: Sabine Hofsäss Telephone: +49 721 926 7641	
24. Signed: Sabine Hofsäss	25. Date: 14.05.2021	26. Time: *

* Information not required, when notified from outside EU.

† The holder of an authorisation referred to under Article 40 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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