

DRINGEND - BITTE SOFORT AUSLIEFERN! IMPORTANT - DELIVER IMMEDIATELY

Rapid Alert Notification of a Quality Defect / Recall		
Add Letter Head of Sender / Meldende Stelle		
1. To / Empfänger:		
FAX		
<input type="checkbox"/>	Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)	0228-207-4636
<input type="checkbox"/>	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)	030-18444-30409
<input type="checkbox"/>	Paul-Ehrlich-Institut - Bundesamt für Sera und Impfstoffe - (PEI)	06103/77-1263
<input type="checkbox"/>	Oberste Landesgesundheitsbehörde	
<input type="checkbox"/>	Oberste Landesveterinärbehörde	
2. Product Recall Class of Defect: I II (circle one)		3. Falsification/Fraud (specify)*
4. Product:		5. Marketing Authorisation Number: * For use in humans/animals (delete as required)
6. Brand/Trade Name:		7. INN or Generic Name:
8. Dosage Form:		9. Strength:
10. Batch number (and bulk, if different):		11. Expiry Date:
12. Pack size and Presentation:		13. Date Manufactured: *
14. Marketing Authorisation Holder: *		
15. Manufacturer†:		16. Recalling Firm (if different):
Contact Person:		Contact Person:
Telephone:		Telephone:
17. Recall Number Assigned (if available):		

18. Details of Defect/Reason for Recall:		
19. Information on distribution including exports (type of customer, e.g. hospitals): *		
20. Action taken by Issuing Authority:		
21. Proposed Action:		
22. From (Issuing Authority):		23. Contact Person: Telephone:
24. Signed:	25. Date:	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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