DRINGEND – BITTE SOFORT AUSLIEFERN! IMPORTANT – DELIVER IMMEDIATELY

Rapid Alert Notification of a Quality Defect / Recall		
Meldende Stelle		
1. To / Empfänger:		FAX/E-MAIL
☐	Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)	0228 207-4636 poststelle@bfarm.de
☐	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)	030 18444-30409 poststelle@bvl.bund.de
☐	Paul-Ehrlich-Institut – Bundesamt für Sera und Impfstoffe – (PEI)	06103 77-1263 pei@pei.de
2. Product Recall Class of Defect: I II (circle one)		3. Counterfeit / 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/Lot Number:		11. Expiry Date:
12. Pack size and Presentation:		13. Date Manufactured:*
14. Marketing Authorisation Holder:*		
15. Manufacturer†: Contact Person: Telephone:		16. Recalling Firm (if different): Contact Person: 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 released the batch in accordance with Article 51 of Directive 2001/83/EC or Article 55 of Directive 2001/82/EC if different.