DRINGEND - BITTE SOFORT AUSLIEFERN! IMPORTANT - DELIVER IMMEDIATELY

Rapid Alert Notification of a Quality Defect / Recall		
Meldende Stelle: Regierungspräsidium Darmstadt Luisenplatz 2 64283 Darmstadt		
1. To / Empfänger:		FAX
☒	Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)	0228-207-3515
☐	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)	01888/412-2303
☐	Paul-Ehrlich-Institut - Bundesamt für Sera und Impfstoffe - (PEI)	06103/77-1234
☒	Oberste Landesgesundheitsbehörde: Hessisches Sozialministerium	0611/817-3850
2. Product Recall Class of Defect: I II (circle one)		3. Counterfeit / Fraud (specify)*
4. Product: Cephazolin Fresenius 2g		5. Marketing Authorisation Number: **6062403.00.00** For use in humans
6. Brand/Trade Name: Cephazolin Fresenius 2g		7. INN or Generic Name: Cefazolin
8. Dosage Form:		9. Strength: 2 g
10. Batch/Lot Number: C3443		11. Expiry Date: 11/2009
12. Pack size and Presentation: 100 ml Vials		13. Date Manufactured: 12.11. – 14.11.2007
14. Marketing Authorisation Holder: Fresenius Kabi Deutschland GmbH, Else Kröner-Straße 1, 61346 Bad Homburg v.d.H		
15. Manufacturer†: Fresenius Kabi Deutschland GmbH Contact Person: Dr. Andrea Bauer (or Marcus Metternich) Telephone: ++49 6172 686 8512 (or -7313)		16. Recalling Firm (if different): Contact Person: Telephone:
17. Recall Number Assigned (if available)		

18. Details of Defect/Reason for Recall: Underfilling		
19. Information on distribution including exports (type of customer, e.g. hospitals): Hospital pharmacies, wholesalers, pharmacies		
20. Action taken by Issuing Authority:		
21. Proposed Action: Recall of the batch C3443		
22. From (Issuing Authority): Regierungspräsidium Darmstadt Luisenplatz 2 64283 Darmstadt	23. Contact Person: Dr. Lenze Telephone: 06151/12-5066	
24. Signed: Dr. Lenze	25. Date: 05.03.2008	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.