


**DRINGEND - BITTE SOFORT AUSLIEFERN! IMPORTANT - DELIVER IMMEDIATELY**

<b>Rapid Alert Notification of a Quality Defect / Recall</b>	
Meldende Stelle Regierung von Oberbayern Maximilianstr. 39 80538 München	
1. To / Empfänger:	FAX
<input type="checkbox"/> Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)	0228-207-3515
<input checked="" type="checkbox"/> Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)	01888/412-2303
<input type="checkbox"/> Paul-Ehrlich-Institut - Bundesamt für Sera und Impfstoffe - (PEI)	06103/77-1234
<input checked="" type="checkbox"/> Bayerisches Landesamt für Gesundheit und Lebensmittelsicherheit (LGL)	09131/6808-5838
2. Product Recall Class of Defect: I <b>II</b> (circle one)	3. Counterfeit / Fraud (specify)* —
4. Product: Estrumate 250 µg/ml, Injektionslösung für Rinder und Schweine	5. Marketing Authorisation Number: * Zulassungs-/Reg-Nr.: 13764.00.00 For use in <del>humans</del> /animals (delete as required)
6. Brand/Trade Name: Estrumate	7. INN or Generic Name: Cloprostenol Sodium
8. Dosage Form: Solution for Injection	9. Strength: 263 µg/ml (corresp. to 250 µg/ml Cloprostenol)
10. Batch/Lot Number: 0619104	11. Expiry Date: 05/2012
12. Pack size and Presentation: 20 ml	13. Date Manufactured: 23.07.2010*
14. Marketing Authorisation Holder: * Intervet Deutschland GmbH Feldstr. 1a D-85716 Unterschleißheim	

15. Manufacturer†: Vet Parma Friesoythe GmbH Sedelsberger Str. 2 D-26169 Friesoythe	16. Recalling Firm (if different): Intervet Deutschland GmbH Feldstr. 1a D-85716 Unterschleißheim  Contact Person: Dr. Isabelle Berthommé  Telephone: 089 / 31006 167	
17. Recall Number Assigned (if available)		
18. Details of Defect/Reason for Recall: Presence of visible particles in the solution for injection.		
19. Information on distribution including exports (type of customer, e.g. hospitals): * Distribution to wholesalers, veterinary pharmacies (tierärztliche Hausapotheken), veterinary faculties, and veterinary authorities Distribution of the affected bulk lot No. 06191 also to Italy, Taiwan, Mexico, Denmark, and Great Britain		
20. Action taken by Issuing Authority: Recall		
21. Proposed Action:		
22. From (Issuing Authority): Regierung von Oberbayern	23. Contact Person: Dr. Hendrik Preuß Telephone: +49 89 2176 3041	
24. Signed: 	25. Date: 09.02.2012	26. Time: 15:30*

\* 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.

*This is intended only for the use of the party to whom it is addressed and may contain information that is privileged, confidential, and protected from disclosure under applicable law. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please notify us by telephone immediately and return it to us at the above address by mail. Thank you*