Company Announcement

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

Huvepharma, Inc. Issues Voluntary Nationwide Recall of Duramycin-10 Due to Stability Failure

For Immediate Release

December 28, 2016

Contact

Consumers

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770-486-7212

Announcement

FOR IMMEDIATE RELEASE – 28 December 2016 – Longmont, Colorado, Huvepharma, Inc., which recently acquired the Longmont Colorado manufacturing facility including the respective FDA registration associated with this recall, is voluntarily recalling 1 lot of Duramycin-10 Soluble Powder, distributed by Durvet, to the consumer level. The product had a stability failure at the 48 month time point. Risk Statement: The product does not have the potential to result in a health risk to any animals that are indicated for use.

To date, Huvepharma, Inc., Durvet, and the previous FDA registration for this product owner, have not received any reports of adverse events related to this recall.

Duramycin-10 is indicated in Calves - for the control and treatment of bacterial enteritis (scours) caused by *Escherichia coli* and bacterial pneumonia associated with *Pasteurella* species, *Actinobacillus pleuropneumoniae*, and *Klebsiella* species susceptible to tetracycline hydrochloride. Chickens **-** for the control of chronic respiratory disease (CRD air sac disease) caused by *Mycoplasma gallisepticum* and *E. coli* and for the control of infectious synovitis caused by *M. synoviae* susceptible to tetracycline hydrochloride. Turkeys - for the control of infectious synovitis caused by *M. synoviae;* and for the control bluecomb (transmissible enteritis, corona viral enteritis) complicated by

organisms sensitive to tetracycline hydrochloride. Swine - for the control and treatment of bacterial enteritis (scours) caused by *Escherichia coli* and bacterial pneumonia associated with *Pasteurella* species, *Actinobacillus pleuropneumoniae*, and *Klebsiella* species susceptible to tetracycline hydrochloride and is packaged in 6.4 oz. packet, with the NDC code 23676 0904**.** The affected Duramycin-10 lot is TSH20002 with the expiration date April of 2017. The product can be identified by the 6.4 oz. packet baring Duramyin-10 in red font and the yellow boxed information describing the product. Duramycin-10 was distributed by Durvet nationwide to wholesale distributors and then further to the retail and customer levels.

Huvepharma, Inc. has notified the distributors of Durvet that purchased/sold Duramycin 10 lot number TSH20002 by letter and telephone and is arranging for return/reimbursement of all recalled product that may be remaining in the market place. Distributors/retailers/consumers that have Duramycin-10 which is being recalled should stop using the product and/or discard any product baring Lot number TSH20002. Consumers with questions regarding this recall of Duramycin-10 and/or wishing to return any unused and unopened packages should or contact Huvepharma, Inc. at 770-486-7212 or email at **customerserviceusa@huvepharma.us (mailto:customerserviceusa@huvepharma.us)**Monday through Friday from 8 AM – 5 PM EST. Consumers should contact their veterinarian if they have experienced any problems in indicated animals that may be related to taking or using this drug product.

- Adverse events involving animals can be reported to the FDA on Form FDA 1932a.
  - FORM FDA 1932a can be found at:
    - **http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/AnimalDrugForms/ucm048817.pdf (http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/AnimalD)**
  - It is preaddressed and pre-postage paid, and can be filled and submitted via US Mail.
  - Call the Center for Veterinary Medicine: 1-888-FDA-VETS. Leave your name, address, phone number, and the brand name of the drug involved. Ask to have a Form FDA 1932a sent to you.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

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