

5100 Paint Branch Parkway  
College Park, MD 20740-3835

M-I-06-9

June 23, 2006

TO: All Regional Food and Drug Directors  
Attn: Regional Milk Specialists

FROM: Milk Safety Branch (HFS-626)

SUBJECT: EXCEDE Sterile Suspension Approval for Lactating Dairy Cattle

On June 2, 2006, Pfizer received FDA approval for a supplement to New Animal Drug Application (NADA) 141-209, for EXCEDE Sterile Suspension. EXCEDE is now approved for use in Lactating Dairy Cattle for the treatment of bacterial respiratory disease via injection at the posterior aspect of the ear where it attaches to the head or base of the ear.

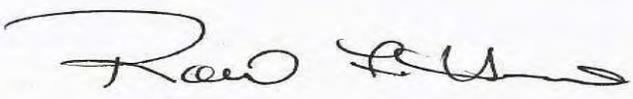
This supplemental approval for EXCEDE Sterile Suspension established a new tolerance for ceftiofur residues in the kidney of 0.4 ppm (400 ppb) in cattle. This is a reduction from the previously established kidney tolerance of 8.0 ppm (8000 ppb). This supplemental approval established a 13-day pre-slaughter withdrawal period for the use of EXCEDE Sterile Suspension in cattle.

The reduction in the kidney tolerance increases the pre-slaughter withhold time for all other cattle products that contain ceftiofur. The products include NAXCEL, EXCENEL RTU, SPECTRAMAST LC and SPECTRAMAST DC. The new pre-slaughter withdrawal periods are: NAXCEL - 4 days, EXCENEL RTU - 3 days, SPECTRAMAST LC - 2 days and SPECTRAMAST DC - 16 days.

For milk, the 100 ppb tolerance and milk discard times for ceftiofur have not changed. EXCEDE Sterile Suspension will have a zero day milk discard period.

An electronic version of this memorandum is available for distribution to Regional Milk Specialists, State Milk Regulatory Agencies and State Rating Officers in your region. The electronic version should be widely distributed to representatives of the dairy industry and other interested parties and will also be available on the FDA Web site at <http://www.cfsan.fda.gov> at a later date.

If you would like an electronic version of this document prior to it being available on the CFSAN Web Site, please e-mail your request to [robert.hennes@fda.hhs.gov](mailto:robert.hennes@fda.hhs.gov).



CAPT Robert F. Hennes, RS, MPH, Chief  
Milk Safety Branch