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College Park, MD 20740-3835

M-I-08-6

March 28, 2008

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

FROM: Dairy and Egg Branch (HFS-316)

SUBJECT: FDA Approval For The Use Of Baytril® 100 (Enrofloxacin) Injectable Solution For The Treatment of Bovine Respiratory Disease (BRD) In Dairy Replacement Heifers Less Than Twenty (20) Months Of Age

Baytril® 100 (enrofloxacin) Injectable Solution has received FDA approval for the treatment of Bovine Respiratory Disease (BRD) in dairy replacement heifers less than twenty (20) months of age.

A label restriction that previously stated: "Not for use in cattle intended for dairy production", prohibited the use of Baytril® 100 in dairy heifers. Due to a recent comprehensive review, FDA's Center for Veterinary Medicine (CVM) granted a modification of that restriction. The label will now read: "Not for use in dairy cattle greater than 20 months of age. Use of enrofloxacin in this class of cattle may cause milk residues."

Baytril® 100 is still prohibited for use in lactating dairy cows, and should be segregated on the dairy farm from those drugs used for lactating animals. It will continue to be a prescription drug, to be used by or on the order of a licensed veterinarian.

If you have any questions or require additional information, please contact:

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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 CFSAN 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).

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Center for Veterinary Medicine

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Dairy and Egg Bureau