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M-I-12-11

August 31, 2012

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

FROM: Dairy and Egg Branch (HFS-316)

SUBJECT: Additional Information Related To The Storage Of Drugs Under Item 15r Of The *Grade "A" Pasteurized Milk Ordinance* (PMO)

The intent of this memorandum is to provide additional clarification to the drug storage requirements as cited in Item 15r-Drug and Chemical Control of the PMO.

"3. Drugs intended for treatment of non-lactating dairy animals are segregated from those drugs used for lactating animals. Separate shelves in cabinets, refrigerators or other storage facilities satisfy this Item."

The Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM) issued the "CVM Update" entitled "FDA Clarifies use of the Term, 'Non-lactating Dairy Cattle'" on February 21, 2012 to address different residue safety requirements for pre-market approval of animal drugs. As part of the New Animal Drug Application (NADA) process, FDA requires different residue safety data from applicants depending on the class(es) of dairy animals for which the drug is indicated. For example: drugs for steers intended for meat are not required to provide milk residue data for human food safety. Drugs approved for use in dry dairy animals, data is required to ensure that unsafe animal drug residues in meat do not occur, and in addition, milk residue data is required. Additional residue data for drugs approved in dry dairy animals is necessary to determine if residues may persist after the dairy animal resumes lactation and the milk from that dairy animal may contain unsafe levels of drug residues for human consumption.

The purpose of the drug labeling and storage requirements of Item 15r of the PMO is to ensure that dairy producers are aware of the labeling directions on the drugs they are using to treat their dairy animals. Dairy producers are reminded to read labels and understand how to properly use and administer animal drugs. When dairy producers have questions regarding the appropriate use of an animal drug, they should consult their veterinarian. The use of drugs in a class of dairy animals, for which they are not approved, outside of an appropriate extra-label use under the supervision of a veterinarian, may lead to residues in meat and/or milk.

For the purpose of Item 15r of the PMO, drugs indicated for use in dry dairy animals shall continue to be stored with the "Non-lactating Drugs". Therefore, drugs intended for use in dairy calves, dairy heifers, dairy bulls and dry dairy cows shall be segregated from drugs for cows that are currently being milked. This required storage system shall also be followed for drugs intended for use in goats, sheep and other dairy animals.

The only drugs that should be stored with the "Lactating Drugs" are drugs that are specifically indicated on the drug label or on a veterinarian's label for extra-label drug use to be used in specific class/species of lactating dairy animals. For the purpose of complying with Item 15r of the PMO, "lactating dairy animals" means those dairy animals that are currently producing milk.

Copies of this memorandum are enclosed for distribution to Regional Milk Specialists, State Milk Regulatory Agencies, State Laboratory Evaluation Officers and State Milk Sanitation Rating Officers in your region. This memorandum should be widely distributed to representatives of the dairy industry, State Veterinarians, State Veterinary and Pharmacy Boards, Veterinarian Professional Organizations and other interested parties and will also be available on the FDA Web Site at http://www.fda.gov at a later date.

If you would like an electronic version of this document prior to it being available on the FDA Web Site, please e-mail your request to Robert.Hennes@fda.hhs.gov.

Robert F. Hennes, RS, MPH
CAPT, U.S. Public Health Service
Dairy and Egg Branch

Attachment: "CVM Update" entitled "FDA Clarifies use of the Term, 'Non-lactating Dairy Cattle'".

FDA Clarifies use of the Term, "Non-lactating Dairy Cattle"

February 21, 2012

The FDA's Center for Veterinary Medicine (CVM) has become aware that the term, "non-lactating dairy cattle," may be confusing and that users could mistakenly interpret it to mean that drugs approved for use in non-lactating dairy cattle are safe when used in dry dairy cows, i.e., in cows between two lactations. The term "non-lactating dairy cattle" includes replacement dairy heifers, replacement dairy bulls, and dairy calves, according to current animal industry standards and a long standing FDA practice. These classes of dairy cattle have not yet, or would never produce, milk for human consumption. The term non-lactating dairy cattle does not include dry dairy cows. Dry dairy cows have previously produced milk for human consumption and will again in the future after completion of the "dry period" between lactations. These standards are reflected in CVM's Guidance for Industry (GFI) #191 (Appendix III, Species and Classes of Major Food Animals).

This is an important human food safety issue because of the potential for residues of drugs labeled for use in non-lactating dairy cattle to be present in milk of the treated cows, as well as in the tissue of the calves born to the treated cows. In order for these drugs to be approved for use in dry dairy cows, residue depletion studies would be necessary to determine whether there are residues in calves born to the treated dry dairy cows and in the milk produced by the treated cows in their subsequent lactation.

FDA is working with sponsors of products approved for use in non-lactating dairy cattle to revise labeling to clarify that dry dairy cows are not non-lactating dairy cattle and therefore should not be treated with drugs labeled for use in non-lactating dairy cattle.

For technical questions related to label revisions, please contact Dorothy McAdams, dorothy.mcadams@fda.hhs.gov.