Statement

April 25, 2012, via email

Food and Drug Administration

"This is a survey program, not an enforcement program. FDA is conducting a double-blinded sampling survey to determine if dairy farms previously identified with drug residue violations in meat may also have unacceptable levels of drug residues in milk. The object is to get an idea of whether the component of the dairy cull industry that has high residue violations in meat also has a problem with milk. While only 7.7% of the cattle slaughtered in the United States are culled adult dairy cattle, tests of tissue samples from these cows have been found to contain drug residue violations that account for 67% of the total violations reported by USDA's Food Safety and Inspection Service during the past 5 years.

"The FDA is collecting milk samples from dairy farms with a history of tissue residue violations that were selected using a risk ranking process (designated as "targeted" samples). The double-blinded sampling survey will also include an equal number of samples from dairy farms that were not selected for inclusion in the targeted list (designated as "non-targeted" samples).

"The survey goal is to collect samples from 900 'targeted' dairy farms that have had tissue residue violations with the highest risk scores. For comparison, it also includes a like number of 'non-targeted' samples taken from dairy farms that are not included in the pool of 'targeted' farms.

"The survey will help determine whether the data from this small subset of the industry is actually a real problem that warrants further follow-up action. FDA routinely uses survey assignments such as this to monitor and constantly improve existing measures for ensuring the safety of nation's food supply. Investigating all potential concerns is important to ensure that the public can retain the utmost confidence in U.S. dairy products.

"Based on investigations conducted by FDA, the drug residue violations involving tissue samples from culled dairy cattle may result from inadequate farm management practices such as the failure to maintain treatment records, failure to identify treated cows, or failure to follow labeled withdrawal times, dosage, duration of treatment, or route of administration.

FDA wants to determine if these practices, which appear to be associated with tissue residues in culled dairy cattle, may also result in unacceptable drug residues in milk, especially from non-beta lactam drugs. Milk is currently routinely tested for beta-lactam drugs. Many of the tissue residues detected by FSIS are for non-beta-lactam drugs such as sulfonamides, aminoglycosides, and non-steroidal anti-

inflammatory drugs. Only two of the top ten drug residues found in tissues from culled adult dairy cattle are beta-lactam drugs."

Siobhan DeLancey, Team Leader for Food, Veterinary and Cosmetic Products
Food and Drug Administration

Statement

May 8, 2012, via email

"The milk sampling assignment began in early January 2012 and is a year long survey. So it will complete in January 2013.

"Once all sample collection and analysis is completed, FDA intends to prepare and publish a report that describes the results of the sampling survey. This report will include results describing the number of samples found to contain drug residues that exceeded any established tolerances or safe levels. For those drugs for which tolerances or safe levels do not currently exist, FDA intends to report the number of samples found to contain a quantifiable level of residues in the context of the established capability of the test method that also provides confirmation of the presence of the drug in question.

"If the sampling survey does detect violative levels of drug residues in milk, FDA believes that such findings reflect a snapshot in time from a limited number of individual dairy farms, and would not pose a significant health risk to consumers. Also, since milk from many different dairy farms is pooled together during processing, the levels of drug residues that might be present in the milk from an individual dairy producer are unlikely to result in residue levels in the pooled milk that would pose a health threat to the consumer.

"This is a very limited program that will look at a small subset of farms that had previous tissue residue violations. FDA believes the information obtained from conducting this sampling survey is important for addressing the question of whether dairy farms with a history of tissue residue violations are more likely to have violative drug residues in milk. Although FDA's sampling survey will not result in regulatory action directed at any individual farms where violations may be found, the sampling survey will help identify whether a problem exists with drug residues in milk. If a problem is identified, FDA is committed to working with State regulatory agencies and the dairy industry to promptly initiate measures to address it. Ultimately, such efforts will serve to further strengthen existing milk safety safeguards. "

Curtis Allen, Media Relations
Food and Drug Administration