May 2, 2011

Margaret A. Hamburg, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Dear Commissioner Hamburg,

On behalf of the Center for Science in the Public Interest (CSPI), and our 750,000 American members/subscribers, we are writing to bring to your attention a proposal working its way through the ongoing National Conference on Interstate Milk Shipments (NCIMS) meeting in Baltimore. On Sunday afternoon, a committee of NCIMS delegates and milk industry representatives voted to eliminate FDA consideration of evidence of drug residues in bob veal calf tissues as an indicator of possible drug misuse on dairy farms. If adopted, this proposal would make it harder for FDA to detect misuse of animal drugs in dairy cattle and, as a result, consumers may be more likely to be exposed to hazardous drugs in milk and milk products and/or resistant strains of human pathogens in the food supply. As the NCIMS meeting is ongoing through this week, and the potential negative human impact of this proposal is high, we urge your prompt attention.

Misuse of antibiotics and other drugs on dairy farms is well documented. From January 2010 to January 2011, USDA’s residue testing program found multiple violations in the use of critically important drugs and illegal drugs in dairy and bob veal cattle from farms throughout the country. In dairy cattle, gentamicin was found in 6 percent of the positive samples, which is a serious violation because the drug is not approved for use in cattle. Gentamicin is absorbed in the body, where it can accumulate and cause toxic effects in humans. Sulfadimethoxine, found in 16 percent of the positive samples from dairy cattle, has not been approved for use in humans, but the side effects in animals, which can include blood and liver disorders, suggest the potential damage to humans from exposure.

Bob veal cattle are beef animals that are up to three weeks of age and 150 pounds. They are harvested directly from dairy farms, and therefore, these cattle are key indicators of drug use on the specific farms and are also important indicators of potential use in dairy cattle residing on those farms. Data from USDA on 735 positive tissue samples from bob veal calves detected 17 different drugs. The second most commonly detected drug was gentamicin (75 violations), and the third most common was tulathromycin (42 violations). Both have zero tolerance levels, and, as noted above, gentamicin is not approved by FDA for use in cattle.

1 Proposal 209 striking the words “and veal” from the list of methods FDA may use to detect potential problems with drug residues under section 6 of the Grade “A” Pasteurized Milk Ordinance (2009 Revision).

2 Based on 11 months of data reported by the USDA’s Residue Violator Alert List. The most commonly detected drug was the antibiotic, neomycin.
While tissue samples in veal calves are not conclusive evidence of improper use of drugs in a dairy’s herd generally, they are indicative of poor management practices on the farm and potential violations. To the extent that drugs can pass to the fetal calf through the placenta and may pass through milk during feeding, the samples can provide evidence of improper management of drugs in dairy cattle on specific farms. As such, bob veal calf tissue samples are useful to FDA in targeting inspections to the dairies most likely to be repeat violators.

Unfortunately, the action contemplated by the NCIMS could deny the agency access to this important tool. CSPI is deeply concerned that the action would create a safe harbor for misconduct on the farm. Consumers want assurance that dairy farms are using drugs in a manner that will not result in drug residues in milk or meat or lead to the increase in antibiotic-resistant pathogens in the food supply.

This proposed action by the NCIMS could erode confidence in the safety of milk products. Potential human impacts from the animal drugs that have been found in the food supply include allergic reactions, nerve damage, severe inflammations, internal bleeding, kidney failure and death. Additionally, overuse of drugs in farm animals is associated with antibiotic resistance in bacteria and reduced effectiveness of antibiotics categorized as “critically important” to human health.

CSPI respectfully requests that FDA exercise its rights to not concur with proposal 209 should it pass in the NCIMS general session later this week, and ensure the agency has fully preserved its ability to use all available evidence to identify dairy farms with inadequate controls on their use of animal drugs.

Lastly, we would like to bring to your attention that there is no consumer representative on the board of the NCIMS. CSPI has put forward David Plunkett, Senior Staff Attorney, to represent consumers on the Board, and that issue will be decided later this week. We hope that we can count on FDA’s support in having the absence of consumer representation at NCIMS addressed immediately.

Sincerely,

Michael F. Jacobson, PhD
Executive Director

Caroline Smith DeWaal
Director of Food Safety

cc Michael Taylor, Deputy Commission of Food