ANIMAL HEALTH INSTITUTE

Representing manufacturers of animal health products

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Richard A. Carnevale

FSIS Docket Clerk
Room 102, Cotton Annex Building
300 12th Street, SW
Washington, DC 20250-3700

Re: Docket #00-026N – Residue Policy

The ANIMAL HEALTH INSTITUTE ("AHI") submits these comments to FSIS' intention to harmonize its procedures with those of the Food and Drug Administration (FDA) with respect to the target tissue/marker residue policy in testing animal tissues for residues of new animal drugs.

AHI is the national trade association representing research-based manufacturers of animal health products – the pharmaceuticals, vaccines and feed additives used in modern food production, and the medicines that keep livestock and pets healthy. Our member companies produce the vast majority of all such products in the United States, as well as the world market.

AHI commends FSIS in its efforts to harmonize its residue policies with those of the Food and Drug Administration and to ensure that meat containing unsafe levels of chemical residues do not enter into commerce. The FDA policy of establishing a target tissue/marker residue for new animal drugs is a sound scientific procedure for ensuring the safety of edible products from food-producing animals. Additionally, the adoption of this policy by FSIS' residue testing program will provide for an economical way to ensure that new animal drugs are used according to the FDA-approved conditions of use. The adoption of this policy assumes that FSIS will use the same analytical methods that FDA used in establishing the tolerances for the marker residue/target tissue combination for a specific animal drug. This assumption will limit the applicability of this policy for many of the screening methods used by FSIS. Before discarding the entire carcass based on a positive screening test in a target tissue, additional testing with more specific methods will be required.

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Discarding the entire carcass when the marker residue in the target tissue exceeds the established tolerance will ensure public health. However, this policy has the potential of discarding tissues other than the target tissue that contain residues that are considered safe by FDA's own safety assessment. The potential for discarding food that does not contain unsafe levels of residues of animal drugs is mitigated by the adoption of tolerances for muscle tissue. As there are only 15 new animal drugs where FDA has established tolerances for residues in muscle, FSIS should, in addition, adopt the tolerances for animal drug residues in muscle tissue that have been established by the Codex Alimentarius Commission. The procedures for establishing Codex tolerances (Maximum Residue Levels) are similar to those used by FDA. Also, FDA and USDA have participated extensively in both the technical and policy deliberations within Codex and have not objected to any of the Codex MRLs.

Sincerely,

Richard A. Carnevale