UNITED STATES ANIMAL HEALTH ASSOCIATION - 2008 RESOLUTION

RESOLUTION NUMBER: **45** **APPROVED**

SOURCE: COMMITTEE ON SHEEP AND GOATS

SUBJECT MATTER: BAN ON EXTRA-LABEL USE OF CEPHALOSPORIN ANTIMICROBIAL DRUGS IN FOOD PRODUCING ANIMALS

BACKGROUND INFORMATION:

On July 3, 2008 the United States Department of Health and Human Services (USDHHS), Food and Drug Administration (FDA) issued an order prohibiting the extralabel use of cephalosporin drugs in food producing animals (*Fed. Reg.* Vol. 73, No. 129). The comment period (Docket Number FDA-2008-N-0326, New Animal Drugs; Cephalosporin Drugs; Extralabel Animal Drug Use; Order of Prohibition) was extended to November 1, 2008. The effective date of the final rule was extended to November 30, 2008.

The extralabel use of cephalosporin drugs for use in sheep and goats is critical to the appropriate treatment of disease and relief of suffering in sheep and goats. Ceftiofur is one of the few antimicrobials approved for respiratory disease in sheep and the only antimicrobial approved for such use in goats. Extralabel use of this drug for other indications (e.g. retained placenta, metritis, septicemia, soft tissue infections), at a higher dose or for duration of treatment exceeding the three-day labeled course of therapy may be medically necessary to prevent animal suffering and appropriately treat disease. Further, there are no antimicrobials currently labeled intramammary for use in sheep and goats. Extralabel use of intramammary cephalosporins labeled use in cattle are medically necessary for the intramammary treatment of mastitis in small ruminant species; no other classes of intramammary preparations have label claims against gram negative mastitis organisms.

The Order of Prohibition is based on evidence that extralabel use of these drugs in food-producing animals will likely cause an adverse event in humans and, as such, presents a risk to human health. No evidence is provided to demonstrate that the use of cephalosporin drugs in small ruminants has contributed to the emergence of cephalosporin-resistant food-borne pathogens, the concern stated in the supporting documents for the Order of Prohibition.

The United States Animal Health Association (USAHA) opposes the FDA Order of Prohibition on extralabel use of cephalosporin antimicrobial drugs in food-producing animals as it applies to small ruminant species. No evidence has been presented that the extralabel use of these drugs in small ruminants presents a risk to public health. The

Order of Prohibition will prevent veterinarians from using medically necessary treatments for disease to relieve animal suffering in small ruminant species.

RESOLUTION:

The United States Animal Health Association (USAHA) requests the United States Department of Health and Human Services (USDHHS), Food and Drug Administration (FDA) to indefinitely delay the effective date of the Order of Prohibition on the Extralabel Use of Cephalosporin Drugs in Food-Producing Animals. USAHA requests that any such ban should be considered on a species-by-species basis and based on evidence generated for each species.

USAHA further requests FDA to conduct slaughter surveillance and collect and share data on the antimicrobial resistance of pathogens of sheep and goats before applying any such prohibition to these species in the future.