UNITED STATES ANIMAL HEALTH ASSOCIATION - 2008 RESOLUTION

RESOLUTION NUMBER: **44** **APPROVED**

SOURCE: COMMITTEE ON SHEEP AND GOATS

SUBJECT MATTER: APPROVAL OF CIDRs®

BACKGROUND INFORMATION:

Reproductive manipulations of sheep and goats such as artificial insemination, embryo transfer and timed matings require drugs, hormones and delivery devices not currently approved or available in the United States (US). Legal and ethical availability of these types of drugs and hormones would facilitate productivity and genetic progress of US flocks and herds and enhance planned reproduction systems for veterinarians and producers, while providing proper and transparent knowledge of the products in use in food producing breeding animals.

CIDRs® (a progesterone-impregnated plastic device for intra-vaginal delivery to synchronize estrus) are labeled and available in many sheep and goat producing countries outside the US. Availability here would level the playing field for US producers. CIDRs® have been expedited through the Food and Drug Administration (FDA), Center for Veterinary Medicine (CVM) Minor Use and Minor Species (MUMS) approval process since the summer of 2006, but they are still not available for use for the fall 2008 breeding season.

RESOLUTION:

The United States Animal Health Association (USAHA) respectfully requests that the United States Department of Health and Human Services (USDHHS), Food and Drug Administration (FDA) complete the label approval process of CIDRs® so that they may be marketed in the United States.

RESPONSES:

U.S. Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine
With respect to Resolution 44(Approval of CIDRs) it is our understanding that NRSP-7 is in the process of obtaining the last "technical section complete" letter required to demonstrate the safety and effectiveness of the progesterone CIDR for sheep. This should happen in the first few monthly so f 2009. Once this final letter is received, NRSP-7 will quickly make all these data available to pharmaceutical sponsors to use in conjunction with their own manufacturing and labeling information support a new animal

drug approval. These data will be compiled into a Public Master File whose availability will be announced on the MUMS (minor use/minor species) page of the FDA-CVM website. The subsequent timing of any new animal drug application and the introduction into the market will be at the discretion of a pharmaceutical sponsor.