

UNITED STATES ANIMAL HEALTH ASSOCIATION – 2007

RESOLUTION NUMBER: 69 APPROVED

SOURCE: COMMITTEE ON SHEEP AND GOATS

SUBJECT MATTER: APPROVAL OF CIDRS[®] AND PREGNANT MARE SERUM
GONADOTROPIN FOR REPRODUCTIVE MANIPULATION
OF SHEEP AND GOATS

DATE: RENO, NEVADA, OCTOBER 18 – 24, 2007

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.

These hormones (progesterone and pregnant mare serum gonadotropin (PMSG), used in combination) 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 (a progesterone-impregnated plastic device for intra-vaginal delivery to synchronize estrus) have been “fast tracked” 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 2007 breeding season.

RESOLUTION:

The United States Animal Health Association (USAHA) respectfully requests that the Food and Drug Administration (FDA) expedite the completion of the approval of CIDRs. We also request that steps be taken to expedite the approval of pregnant mare serum gonadotropin (PMSG) through the Minor Use and Minor Species (MUMS) process to allow enhanced reproduction systems in sheep and goats.

RESPONSE:

Food and Drug Administration, Center for Veterinary Medicine

While we appreciate your interest in getting an expedited decision on the CIDRs and PMSG, unfortunately, neither one of these products qualify for expedited review.

Expedited review is granted for therapeutics can treat a life-threatening condition in animals. We recognize that the CIDRs has been designated as a minor species product but it still must meet all of the relevant safety and efficacy requirements for new animal drugs. We recommend that you contact the manufacturers of PMSG to determine the plans for the products, as we do not have the type of information you are interested in. For additional information and clarification on the MUMS program please do not hesitate to contact me by telephone at 240-276-9005 or by e-mail, margaret.oeller@fda.hhs.gov