RESOLUTION NUMBER: 29                   APPROVED

SOURCE:               COMMITTEE ON SHEEP AND GOATS

SUBJECT MATTER:        MINOR USE ANIMAL DRUG PROGRAM

BACKGROUND INFORMATION:

The approval of animal drugs for use in minor species is critical to the appropriate treatment of sheep and goat disease and to the maintenance of animal health. The National Research Support Program-7 (NRSP-7) provides much-needed and valuable services to the sheep and goat industries throughout the United States. The continued work of this program will be essential to the sustainability and growth of the industry through the availability of the United States Food and Drug Administration (FDA)-approved medications for use in sheep and goats.

The United States Animal Health Association (USAHA) supports and appreciates the efforts of the NRSP-7. The research conducted under this program will be essential to the sustainability of the small ruminant industries and to the maintenance of sheep and goat health. The USAHA acknowledges the importance of research conducted under the NRSP-7.

RESOLUTION:

The United States Animal Health Association urges Congress to include a permanent funding mechanism for the National Research Support Program-7 (NRSP-7) program and urges the United States Food and Drug Administration and the United States Department of Agriculture to include funding for the NRSP-7 in their budget requests at a level that meets the needs of minor use and minor species requests.
December 10, 2012

David L. Meeker, Ph.D., M.B.A.
President
United States Animal Health Association
4221 Mitchell Avenue
Saint Joseph, Missouri 64507

Dear Dr. Meeker:

Thank you for your letter dated November 19, 2012, sent to Dr. Bernadette Dunham, Director of the U.S. Food and Drug Administration’s Center for Veterinary Medicine (FDA-CVM) sharing your 2012 Resolution No. 29: Minor Use Animal Drug Program which states, “The United States Animal Health Association urges Congress to include a permanent funding mechanism for the National Research Support Program-7 (NRSP-7) program and urges the United States Food and Drug Administration and the United States Department of Agriculture to include funding for the NRSP-7 in their budget requests at a level that meets the needs of minor use and minor species requests.”

FDA-CVM is a strong proponent of the need to fund research to support the approval of needed new animal drugs for minor uses and minor species. This commitment extends beyond the activities of the NRSP-7 Minor Use Animal Drug Program. Through our Minor Use/Minor Species (MUMS) Designation program, FDA-CVM budgets for and provides grants to support safety and effectiveness studies to support approval of MUMS products. NRSP-7 researchers are eligible to apply for these grants and have done so successfully. These are competitive grants available to any sponsor pursuing approval of a MUMS product that has “designated” status. These grants are helpful to the researchers in the NRSP-7, but they are not a substitute for the needed funding from USDA to administer the program.

It should also be noted, that while it does not directly fund NRSP-7 as a budget item, for decades FDA-CVM has provided one staff member to serve as the FDA Liaison to the Minor Use Animal Drug Program (NRSP-7). To date, the partnership of the liaison with the members of the NRSP-7 has led to the approval of 28 new animal drugs for use in minor species of agricultural importance.

The NRSP-7 program has been a successful and efficient program and its continuation is of significant value to the stakeholders involved in raising minor species of agricultural importance.
FDA-CVM has every intention of continuing to provide a liaison to the NRSP-7 program and plans to continue to offer MUMS grants for designated products to researchers working in support of approval of designated MUMS products, including those working on NRSP-7 projects. These actions benefit the NRSP-7 program and do not require FDA to include funding specifically for the NRSP-7 program in its budget.

Your resolution should be directed only to the USDA to focus on the need for their budget to reflect support of this important program.

We appreciate you sharing your resolution and your ongoing interest in and support of our work.

Sincerely yours,

Bernadette M. Dunham, D.V.M., Ph.D.
Director, Center for Veterinary Medicine