



December 19, 2017

United States Animal Health Association
Attention: Barbara C. Determan
President, USAHA
4221 Mitchell Ave.
St. Joseph, MO 64507

Re: Resolution 20: Minor Use Animal Drug Program

Dear Ms. Determan:

Thank you for your letter of support for the USDA's Minor Use Animal Drug Program. Your organization's resolution reads as follows:

The United States Animal Health Association urges Congress to authorize a permanent funding mechanism for the Minor Use Animal Drug Program and urges the United States Food and Drug Administration and the United States Department of Agriculture to include permanent funding for the Minor Use Animal Drug Program in their budget requests at a level that meets the needs of minor use and minor species requests.

We cannot speak for the USDA or Congress, but will confirm that the FDA is committed to the support of the Minor Use Animal Drug Program (MUADP). Although the MUADP is part of the Department of Agriculture's National Institute of Food and Agriculture (NIFA), FDA's Center for Veterinary Medicine (CVM) has provided a full-time FDA Liaison to the program since its inception. This person, currently Dr. Amy Omer (amy.omer@fda.hhs.gov), serves to facilitate all interactions between the University researchers, pharmaceutical sponsors, and the CVM's review staff to help projects complete the approval process. To date, this program has seen 29 new animal drugs approved for minor species of agricultural importance due to its efforts.

The USDA recently had a series of "Calls to Conversation" to get stakeholder input about its Tactical Science Programs, including the MUADP. FDA/CVM sent a representative, Dr. Meg Oeller (Margaret.oeller@fda.hhs.gov), to these meetings to make certain that FDA's support for the program was known. For more information about these meetings, see: <https://nifa.usda.gov/resource/biosecurity-protect-americas-food-and-agricultural-system> .

FDA/CVM also has a grants program that helps to defray the costs of studies to support FDA approval of Minor Use/Minor Species (MUMS) Designated new animal drugs. Investigators working in partnership with sponsors are eligible to apply for these grants. MUADP investigators have started to take advantage of this program and we hope that they will do so even more in the future. Information on the MUMS Designation program and its grants is available on our website:

<https://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/MinorUseMinorSpecies/ucm064838.htm> . We appreciate that these grants will not replace the need for a consistent, stable funding source for the MUADP, but we think they are a helpful adjunct.

FDA/CVM is committed to increasing the legal availability of new animal drugs for minor uses and minor species. We are trying to accomplish this through the programs authorized by the Minor Use & Minor Species Animal Health Act of 2004 as well as through cooperation with the USDA and other State and Federal agencies to gather the information needed to support these projects.

Please see our webpage for a description of the programs that we have to support minor uses and minor species:

<https://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/MinorUseMinorSpecies/default.htm>

The MUADP is a major part of this effort and we very much appreciate and join in your support of this worthwhile program.

Sincerely,

A handwritten signature in black ink, appearing to read "S. M. Solomon".

Steven M. Solomon, DVM, MPH
Director
Center for Veterinary Medicine