



G-003664-G-0002-OT

National Turkey Federation
Attention: Beth Johnson
1225 New York Avenue, NW
Suite 400
Washington, DC 20005

Re: Minor use determination

Dear Ms. Johnson:

In response to your submission dated October 19, 2018, the Office of Minor Use & Minor Species Animal Drug Development (OMUMS) has determined that the following proposed indication constitutes a minor use in a major species:

For the control of mortality caused by blackhead disease (histomoniasis) in flocks of turkeys where the disease has been diagnosed

The survey data you provided regarding the annual rate of occurrence of blackhead outbreaks in turkeys in the U.S. was adequate for us to make this determination. We concluded that the estimated rate of occurrence of blackhead in 1 to 2 million turkeys is sufficiently below the established small number of 14,000,000 turkeys on an annual basis and that the uncertainty associated with your estimate is acceptable. Therefore, this proposed indication constitutes a minor use in a major species.

However, there is insufficient information for us to determine minor use status with respect to the following proposed indication:

For the prevention of mortality in turkeys at high risk of developing blackhead disease (histomoniasis) due to being raised on a farm with an historical incidence of blackhead

To support this second indication, we need additional information, including:

1. a description of the survey methodology used by Dr. Steven Clark, including how representative the surveys are of the annual turkey production in the U.S.,
2. an estimate of the number of farms in the U.S. that have had previous outbreaks of blackhead,
3. an estimate of how long after a prior outbreak a farm would be considered a source of infection for a further outbreak,
4. an estimate of the number of turkeys that would typically be raised annually "on a farm with an historical incidence of blackhead", and finally

5. an estimate from the NTF regarding the number of turkeys on an annual basis that would be eligible for prevention of mortality on farms with a prior history of blackhead.

The best source of this information may be Dr. Steven Clark, as both a recognized expert in turkey disease and production, a highly regarded representative of the turkey industry, and the creator of the survey cited above. In all cases in which estimates of typical flock or farm size can be supported by USDA or other published sources of turkey production-related information, you should provide those supporting data.

We encourage you to make another submission to us containing the above information so that we can conduct a minor use determination for the second indication. Please use the contact information below.

You should refer to the date of this letter and to file number G-003664-G-0002-OT for future correspondence regarding this submission. Please send paper submissions to Dr. Meg Oeller, Director, Office of Minor Use & Minor Species Animal Drug Development, FDA Center for Veterinary Medicine, Document Control Unit/HFV-199, MPN 2, E150, 12225 Wilkins Avenue, Rockville, MD 20852. Thank you.

Please feel free to contact me at (240) 402-0566, if you have any questions.

Sincerely,

M.R. Oeller, DVM

Meg Oeller, DVM
Director
Office of Minor Use & Minor Species
Animal Drug Development
Center for Veterinary Medicine