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Division of Dockets Management (HFA-305)
Food and Drug Administration, HHS
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Docket No. 2008N-0011 and RIN 0910-AG03 (21 CFR Part 516): Defining Small Number of Animals for Minor Use Designation

Dear Sir or Madam:

I am writing on behalf of the American Veterinary Medical Association (AVMA), established in 1863 and the largest veterinary medical association in the world. As a not-for-profit association established to advance the science and art of veterinary medicine, AVMA is the recognized national voice for the veterinary profession. The association's more than 76,000 members comprise approximately 86% of U.S. veterinarians, all of whom are involved in a myriad of areas of veterinary medical practice including private, corporate, academic, industrial, governmental, military, and public health services.

The AVMA appreciates CVM's attempt, for regulatory purposes, to use a quantitative, approach to define a "small number of animals" for each of the seven major animal species, to determine whether the use of any particular product meets the intention of Congress in considering the 'minor use' of any drug for the treatment of a disease or condition in a major species. The AVMA fully understands that, for a variety of reasons, that this is a challenging undertaking.

After reviewing the FDA proposed approach we reiterate many of the issues raised in our January 23, 2006 comments on this issue, most notably that the agency needs to remain extremely flexible and nimble in the interpretation of what constitutes a 'minor use', if the full intent of Congress is to be upheld. Most notably we have concerns that a single formula approach will not accommodate the variability inherent in diseases or conditions that occur infrequently or in limited geographical locations.

As pointed out in 2006, the very nature of 'minor diseases or conditions' creates a complex epidemiological picture that may change over time depending on a multitude of unpredictable factors such as the pathobiology and transmission rates of the disease or condition. We emphasize that AVMA does not believe the system used for human orphan drug determination (a specific number of cases of a specific disease or condition as a percentage of the population) will work for "minor use" animal drugs. For FDA to establish a numeric criterion for designating a "minor use" drug, the only justifiable and defensible approach would be one based on epidemiology. The burden on a sponsor for determining a multitude of constantly changing, highly unreliable and in many cases unavailable epidemiological data that affect a "minor" disease and animal population, needed for determining the probability a drug being used in a small number of animals, may be an unattainable goal and is likely to be a direct disincentive to seeking MUMS designation. It is well established that, unlike human populations, animal population sizes and diseases are highly dynamic and are influenced by consumer demand, market forces

and economics, regulatory, and producer, industry, state and federal prevention, control and eradication programs in place at any point in time. The AVMA is well aware of evolving national programs within the USDA (e.g. Centers for Epidemiology and Animal Health – CEAH); National Center for Animal Health Surveillance – NCAHS; Agriculture Marketing Service – AMS); Economic Research Service – ERS) that seek to estimate both population size of all major species and their diseases. However, these data are collected for reasons other than, and unsuitable for determining “minor disease or conditions”, and the information is incomplete. Simply, on epidemiological grounds currently it is almost impossible to justifiably establish a fixed prevalence (or percentage of the total or sub-population) of a “minor disease” in any animal species without reliable data.

The consequence of this, particularly for emerging infectious and contagious diseases (that are quite likely to initially affect only a small number of animals) is that without drugs to treat small numbers of animals (viz. ‘minor uses’), the response to emerging diseases, animal health and welfare and, potentially, public health may be compromised.

We therefore suggest that FDA may like to postpone adopting the proposed methods of quantitatively determining “minor uses” until these have been tested in one or more real (not theoretical) scenarios. However, if FDA does adopt a quantitative approach at this point in time we strongly suggest that the agency review this approach on a regular basis – at least every five years or less – to determine if the approach is viable. Furthermore, the FDA must be prepared to modify the regulations as necessary should the approach not fully meet Congress’ intent for making drugs for minor conditions and diseases in all major species available for use.

We hope these comments provide FDA the input sought and look forward to seeing practical and workable regulations in place. Should you need further explanation of any comments offered please feel free to contact Dr. David Scarfe (847-285-6634; dscarfe@avma.org)

Most sincerely,



W. Ron DeHaven DVM, MBA
Executive Vice President

WRD/ADS