



January 6, 2005

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

RE: Docket No. 2004N-0480, MUMS Implementation

Dear Sir or Madam,

We are quite excited about the recent passing of the MUMS legislation and hope that it will be quite successful. We would like to take a moment and offer the following comments on the implementation of the MUMS program.

Regardless of the size of the drug sponsor company, there are always multiple demands on resources—money, personnel and time. It just makes sense that the higher grossing, higher profit products will receive these resources leaving very little for the lower budget projects, such as a MUMS product.

In order to be successful, and to actually see fruits of the new legislation, we suggest that the agency come up with some creative ways of satisfying the requirements to prove safety and efficacy of the minor use or minor species products so that a product could be approved without a great demand on a sponsor's resources. Our suggestions are:

1. Accept previously published data, regardless of the ability to access all the raw data
2. Extrapolate from data in other species.
3. Response time from the agency needs to be short.

We are not suggesting that all the data used to support a MUMS product be from these other sources, but a good portion of it could be. Practicing veterinarians

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are currently treating minor species and/or minor diseases based on information gathered from these two areas and consider this acceptable.

Review and response times from the agency must be short so that resources are not tied up in these smaller projects. A company will not invest, or tie-up, capital in a study and the other components of a drug application and then wait months for an answer.

Please take our comments into consideration. We are looking forward to sponsoring products for MUMS and hope it is a successful program.

Sincerely,



Jenaay M. Brown DVM
Director, Regulatory Affairs