From: "BeeMac201" <BeeMac201@aol.com>, on 1/20/98 10:10 PM:
To: George Mitchell@OD@FDACVM

Dr. Bert Mitchell:
I have the following comments on the discussion draft of MUMS Proposed Report 98 JAN 20 PM12:57
CVM 97132 December 19, 1998.

-p. 23 Adding residue depletion studies to the category "significant new data" to provide exclusivity would be a very positive step.

For minor species food animal submissions the major hurdle is the establishment of the Human Food Safety package in a major species. All of the minor species incentives together , with the exception of direct grants to pay for the human food safety package, will not overcome the costs of the support toxicology and residue depletion studies needed for a USA registration.

-p. 31 Expert review panels-non food animals.

The Drug Information Division of the US Pharmacopia has an advisory panel on Veterinary medicine and has prepared monographs of drugs for animal use. The drug monographs provide information that appears to be similar to that requested for the proposed expert review panels. These monographs appear yearly in the September supplement DI update to the USP Drug Information for Professionals published by USP. The current chair of this group is Dr. Corey Langston of Mississippi State University (phone number 601- 325-1265. Members of the panel include Dr. R. Teske FDA-CVM retired and Dr. S. Sundloff FDA-CVM Center Director. A listing of the compound monographs prepared to date and in preparation will be faxed to you for your information.

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