



October 28, 2004

RE: Docket No. 2004D-0422 - Draft Guidance for Industry: Animal Drug Sponsor Fees under the Animal Drug User Fee Act (ADUFA)

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

Biotechnical Services, Inc. (BSI), a contract research organization whose clients include companies developing animal health products, appreciates the opportunity to comment on CVM's draft Guidance for Industry #173: Animal Drug Sponsor Fees under the Animal Drug User Fee Act (ADUFA).

The draft guidance states that CVM would likely establish an INAD file when advance materials were submitted for a meeting with CVM to discuss investigational or submission requirements and that as a consequence (1) the submitter would be considered an animal drug sponsor, (2) the submitter would have an investigational animal drug submission pending review after September 1, 2003, and (3) the submitter would be subject to the animal drug sponsor fee. [page 4, and appendix 1, example 7].

BSI respectfully requests CVM reconsider this interpretation of the sponsor fee provisions of ADUFA for the following reasons:

- (1) Advance materials submitted for an initial meeting with CVM to discuss investigational and submission requirements for a potential animal drug product do not fulfill the definition of an "investigational animal drug submission." They do not fulfill the definition because they are not information submitted "for the purpose of enabling the Agency to evaluate the safety or effectiveness of an animal drug application or supplemental animal drug application in the event of their filing."
- (2) Only selected companies – those having no animal drug products or active INAD files and who are considering embarking on the development of an animal drug product – will be affected. Information about investigational and submission requirements received at the initial meeting influences a potential sponsor's decision to continue with or terminate product development. The imposition of a sponsor fee for the initial meeting with CVM has the effect of charging these companies a fee before they have made firm product development commitments.
- (3) Interpreting the sponsor fee provisions as stated in the draft guidance could have the unintended consequence of discouraging development of new, innovative therapeutic and production products for animals. This would be counter productive to the stated mission of CVM/ONADE to protect the public health by ensuring an adequate amount of safe and effective new animal drugs to meet the therapeutic and production needs of animals.

BSI encourages the Agency to defer imposition of the sponsor fee until a company that does not otherwise qualify as a sponsor makes a protocol or NCIE submission.

Sincerely,

Judith C. McDowall
President