Appendix 1

Person Making Submission	Is the Person an "Animal Drug Sponsor?"	The submission	Will the Animal Drug Sponsor Fee be Assessed?
1. The person has approved NADAs and INAD files	Yes	A description of a product under development and a question whether it is a new animal drug regulated by FDA	No. An answer regarding jurisdiction is an administrative action and does not subject an animal drug sponsor to a fee.
2. The person has one INAD file	Yes	A request to terminate the INAD file that is submitted after Sept. 1, 2003	No. This request for administrative action is not an "investigational animal drug submission." After CVM terminates the INAD files, the person will no longer be an animal drug sponsor.
3. The person has an approved NADA and an INAD file	Yes	A request to terminate an INAD file is submitted after Sept. 1, 2003	No. The request for administrative action does not trigger assessment of the animal drug sponsor fee.
4. The person has approved NADAs and/or INAD files	Yes	An NADA, supplemental NADA, or an investigational animal drug submission submitted prior to, but still pending after, Sept. 1, 2003	Yes

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5. The person has approved NADAs and/or INAD files	Yes	An NADA, supplemental NADA, or an investigational animal drug submission submitted after Sept. 1, 2003	Yes
6. The person does not have any approved NADAs, does not have any INAD files, and has not conducted clinical trials	No	A request for a meeting solely to discuss FDA's administrative processes for submitting investigational information, an NADA, or a supplemental NADA	No. The person is not an animal drug sponsor and the submission does not change the status.
7. The person does not have any approved NADAs, does not have any INAD files, and has not conducted clinical studies	No	A request for a meeting to discuss investigational or submission requirements	Yes, when a person requests a meeting to discuss investigational or submission requirements, they are requesting presubmission conference and need to provide advance materials. FDA will establish an INAD file for these materials and the person will become an animal drug sponsor. FDA reviewers will evaluate information submitted for the purpose of enabling FDA to evaluate safety or effectiveness if a new animal drug application is submitted.

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8. The person does not have any approved NADAs and does not have any INAD files	No	A Notice of Claimed Investigational Exemption (NCIE) submitted prior to shipping new animal drug for clinical tests in animals and after Sept. 1, 2003	Yes. When the person files a claim for investigational exemption, FDA establishes an INAD file and the person becomes an animal drug sponsor subject to an animal drug sponsor fee.
9. The person submitted NCIEs and started clinical studies before September 1, 2003, and currently has no submissions pending	Yes (see # 8)	A request for a meeting solely to discuss FDA's administrative processes for submitting investigational information, an NADA; the request is made after Sept. 1, 2003	No. A request only for administrative action will not trigger assessment of the animal drug sponsor fee.

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10. The person does not have any approved NADAs, does not have any INAD files, and has begun foreign clinical studies to support approval in the U.S.	No	A request for a meeting to solely to discuss FDA's administrative processes for submitting investigational information, and NADA, or a supplemental NADA is submitted after Sept. 1, 2003	Qualified No. If no new animal drug is shipped from the U.S. to conduct clinical studies, an INAD has not previously been established, and the meeting requested is solely to discuss administrative processes, the person is not an animal drug sponsor and does not become a sponsor or subject to a fee by virtue of the request for a meeting. It is, however, recommended that persons seeking approval of a new animal drug in the U.S. discuss with the FDA the applicability of foreign studies to support U.S. approval. If a presubmission conference is requested to discuss investigational and submission requirements, the request for the presubmission conference would trigger assessment of an animal drug sponsor fee (see #7).
11. The person has only one approved new animal drug application for a new animal drug intended only for use in minor species	Yes	An NADA, supplemental NADA, or investigational animal drug submission for a new animal drug intended only for use in minor species is pending as of, or submitted after 9/1/03.	Yes. Because this person has a submission pending after Sept. 1, 2003, FDA is required to assess an animal drug sponsor fee. The animal drug sponsor may, however, request a fee waiver or reduction (see Guidance #170.)