Appendix 1

Column 1	Column 2	Column 3	Column 4
Person Making the Submission	**Based on the information in Column 1,was the Person an "Animal Drug Sponsor" prior to the making the submission described in Column 3?**	**The submission**	**Is the person an Animal Drug Sponsor subject to the Animal Drug Sponsor Fee?**
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 are submitted after September 1, 2003	No. There is no submission pending after September 1, 2003; this request for a determination of jurisdiction is not "an investigational animal drug submission" 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." In addition, 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. This request for administrative action is not an "investigational animal drug submission."
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
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 made after September 1, 2003, for a meeting solely to discuss FDA's administrative processes for submitting investigational information, an NADA, or a supplemental NADA	No. This request to discuss FDA's administrative process for submitting information to FDA is not an "investigational animal drug submission."

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7. The person does not have any approved NADAs, does not have any INAD files, and has not conducted clinical studies	No	A request pending as of, or submitted after, September 1, 2003, for a meeting to discuss investigational or submission requirements	If a person wishes to discuss investigational or submission requirements and provides advance materials for FDA to review, FDA will review the advance materials and would likely establish an INAD file for these materials. If so, the person would be an animal drug sponsor, would have an investigational animal drug submission pending after September 1, 2003, and would be subject to an animal drug sponsor fee.
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 an NCIE, FDA establishes an INAD file and the person becomes an animal drug sponsor. Because the submission is pending after September 1, 2003, the animal drug sponsor is 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 for administrative action only is not an investigational animal drug submission. Because there is no submission pending after September 1, 2003, the animal drug sponsor does not become subject to an animal drug sponsor fee by virtue of this request.
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	No. However, CVM recommends 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 person wishes to discuss investigational or submission requirements and provides advance materials for FDA to review, FDA will review the advance materials and would likely establish an INAD file for these materials. If so, the person would be an animal drug sponsor, would have an investigational animal drug submission pending after September 1, 2003, and would be subject to an animal drug sponsor fee (see #7).

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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, qualify for a fee waiver or reduction. Further information regarding fee waivers and reductions, including those based on minor species, is provided in Guidance #170.