of the Bureau of Veterinary Medicine will make the initial determination on whether good cause has been shown. If the Director concludes that good cause has not been shown, the applicant may appeal this decision to the Assistant Commissioner for Public Affairs, whose decision on the matter will be final.

(b) Prior to the termination or discontinuation of an INAD or the approval of an NADA, all data and information submitted or incorporated by reference in the INAD file are confidential and not available for public disclosure except to the extent previously made public in an authorized manner by the sponsor or master file holder.

(c) All data and information submitted or incorporated by reference in an NADA file (including an INAD, supplemental NADA, § 135.14a or § 135.14b report, master file, or other similar submission) shall be clearly marked confidential if the sponsor or applicant considers it to be confidential and exempt from public disclosure. Adequate grounds must be given to justify the confidentiality of each item so marked. All data and information previously made public in any authorized manner will not be retained by the Food and Drug Administration as confidential unless extraordinary circumstances are shown. Any request for confidentiality shall state that the data or information so marked has not previously been made available to any person who is not an employee or paid consultant or shall explain why the data or information should remain confidential in spite of such prior disclosure. Applying the guidelines in this section and in Subpart B of Part 5, the Director of the Bureau of Veterinary Medicine will make the initial decision on whether information marked confidential will be available for public disclosure. If the Director concludes that an item so marked is not exempt from public disclosure, the applicant or master file holder will be so informed and will be given an opportunity to appeal that decision to the Assistant Commissioner for Public Affairs, whose decision on the matter will be final.

(d) Unless otherwise publicly disclosed, no safety and effectiveness data and information submitted with or incorporated by reference in an NADA file are available for public disclosure until the Food and Drug Administration withdraws approval of the NADA or determines that the drug is not a new animal drug or may be marketed pursuant to an abbreviated NADA. All such data and information are available for public disclosure when the Food and Drug Administration withdraws approval of the NADA or determines that the drug is not a new animal drug or may be marketed pursuant to an abbreviated NADA, unless extraordinary circumstances are shown.

(e) A protocol for a test or study is available for public disclosure unless an adequate showing is made that it constitutes a trade secret or confidential information because it is unique, has not previously been disclosed in an authorized manner to anyone other than a company employee or a paid consultant, has been developed at significant cost and provides a competitive advantage.

(f) Manufacturing methods or processes, including quality control procedures, are not available for public disclosure except to the extent previously disclosed to the public by the sponsor or applicant or master file holder.

(g) An assay method is not available for public disclosure except to the extent previously disclosed to the public by the sponsor or applicant or master file holder except pursuant to section 512(i) of the act or unless it must be available to permit other manufacturers to comply with limits established for the drug under an old animal drug monograph or an abbreviated NADA. The availability of an assay method will be included in the regulation.

(h) All safety and effectiveness data and information contained in an INAD file which has been discontinued or terminated are available for public disclosure unless extraordinary circumstances are shown.

(i) Adverse reaction data and information are available for public disclosure with the names of individuals deleted.

(j) Production and sales data and information are not available for public disclosure except to the extent previously disclosed to the public.

(k) Quantitative or semiquantitative formulae are not available for public disclosure except to the extent previously disclosed to the public. A list of all ingredients contained in a product or a list of all products containing a specified ingredient or a list of all products known to possess a particular characteristic or any similar list is available for public disclosure. A particular ingredient (or product containing that ingredient) may be excluded from any such list upon a showing that the ingredient is a trade secret in that it is unique, is important to the product, and is not known to competitors.

(l) Every person who has submited an INAD or NADA file prior to the effective date of this section may submit in writing to the Food and Drug Administration, within 180 days after such effective date, a request that specified data and infor-