tors and are not the type of valuable commercial information customarily regarded as privileged. For future petitions or forms, such justification shall be provided when the petition is submitted. An opportunity will be provided for appeal if the data or information are regarded by the FDA as not confidential. Nonconfidential information will be released at the time the food additive or color additive regulation or antibiotic drug monograph is promulgated. For petitions or forms already submitted, manufacturers will be given 180 days within which to submit in writing a justification for holding specified information in such petitions confidential.

b. The safety and effectiveness data contained in FDA files relating to new drugs and new animal drugs may or may not represent valuable trade secret and confidential information depending upon the legal status of the particular drug. Nonpublic safety and effectiveness data and information relating to drugs for which a new-drug application (NDA) or a new animal drug application (NADA) is required clearly represent highly valuable material, since the law provides that a competitor cannot market or use the drug without first submitting such data and information to FDA for approval. With respect to drugs that may be marketed on the basis of an abbreviated application or that are "old drugs" which do not require premarketing approval, no such competitive advantage attaches to the safety and effectiveness data and information, and it therefore no longer represents valuable commercial property for which confidentiality may be maintained unless extraordinary circumstances can be shown. Similarly, when an application has been filed and approval has been withdrawn, the safety and effectiveness data and information contained therein provide no competitive advantage and will not be maintained as confidential. (Disclosure or nondisclosure of such data must depend upon the legal status of the product or ingredient as determined by FDA and not as determined by a manufacturer or a competitor, since FDA is not bound by anyone else's determination of that legal status.)

Accordingly, for such data already contained in FDA files for which disclosure will otherwise be permitted, the applicants will be granted 180 days within which to designate in writing the specific data that they believe remain confidential. In special cases where requests for information are pending, FDA will ask for an immediate reply on this matter. Adequate justification for confidentiality must be given. In order to avoid unnecessary work, FDA may wait for a request for public disclosure of a particular document before ruling on a request for confidentiality of that document. Where confidentiality is not requested or the justification is inadequate, the data will be made available for public disclosure. All such data otherwise previously made available to the public will not be held as confidential.

For applications submitted to FDA in the future, all data and information regarded as confidential must be clearly marked. Until the ingredient or product is classified by FDA as a human drug or animal drug that is no longer a new drug or new animal drug or that may be the subject of an abbreviated application, all such data will be retained as confidential. Thereafter, it will become publicly available unless extraordinary circumstances can be shown. Since the data and information in a new NDA are confidential and thus cannot be disclosed, in lieu thereof every future application or supplement will be required to contain a comprehensive summary of all safety and effectiveness data. When the application and the summary are approved by FDA, the summary will become publicly available. This summary will not constitute the full reports required by the statute for a competitor to obtain approval of an identical product.

The safety and effectiveness data in an investigational new drug plan (IND) or an investigational new animal drug plan (INAD) which has been terminated or discontinued and in an NDA or NADA for which FDA has withdrawn approval for any reason pursuant to section 505(e) or section 512(e) of the Federal Food, Drug, and Cosmetic Act will be available for public disclosure unless extraordinary circumstances are shown.

6. Studies, tests, and other research often include the names of patients or research subjects. Such names or other identifying characteristics in data or information disclosed to the public will be deleted to avoid invasion of personal privacy.

7. Quantitative or semiquantitative product formulae contained in applications and petitions are valuable commercial property that provide an advantage over competitors and therefore will not be made publicly available unless they have otherwise previously been disclosed (e.g., in a patient or scientific article) by the manufacturer. A list of all ingredients in a product, or a list of all products containing a particular ingredient, or similar lists will be available for public disclosure unless a particular ingredient is shown to be a trade secret.