8. Assay methods contained in applications and petitions are methods or processes which are trade secrets and valuable commercial property that provide an advantage over competitors and therefore will not be publicly disclosed unless other, more specific, statutory provisions so require. The food additive, color additive, new drug, and new animal drug provisions of the law require FDA to determine safe conditions of use. An assay method may or may not be required as part of that determination. When public disclosure of an assay method is required to assure safety (which will usually be the situation with food additives, color additives, old human and animal drugs, and human and animal drugs that may be the subject of abbreviated applications), the confidentiality of the method will not be retained.

9. Manufacturing processes are methods or processes which are trade secrets and valuable commercial property that provide an advantage over competitors and therefore will not be made publicly available unless they have otherwise previously been disclosed by the manufacturer.

10. Protocols (methods and procedures) for tests or studies will be made available to the public except upon a showing that they constitute trade secrets or confidential information because they are unique, have not previously been disclosed to any member of the public (other than a paid consultant), have been developed at significant cost, and provide a competitive advantage.

11. The existence of pending new drug applications will be made known by a list of such pending matters. Each applicant will, however, be given an opportunity to persuade FDA that particular circumstances justify excluding his application from the list.

12. The Food and Drug Administration has in the past received, and will continue to receive, a wide variety of information that is voluntarily submitted to the agency by members of the public, physicians, the regulated industries, and professional organizations and that is not a part of any application or petition or otherwise required to be submitted. All such information submitted in the future will be publicly disclosed unless it is marked confidential and adequate justification for its confidentiality is stated. In the event that the Food and Drug Administration concludes that adequate justification for confidentiality is not shown, the person submitting the information will be given the opportunity either to withdraw the information or to submit it without a request for confidentiality. Since submission of this data and information could not be compelled and the Food and Drug Administration is thus dependent upon the goodwill of individuals and companies to receive this information, a somewhat more narrow disclosure policy will be followed than is the case with data and information required to be submitted. For example, adverse reaction and complaint data for new drugs, which are required to be submitted to FDA, will be available for public disclosure with only the names of patients and physicians deleted; but adverse reaction and complaint data for foods, devices, cosmetics, and hazardous substances voluntarily disclosed by companies, which are not required to be submitted to FDA, will be available for public disclosure only in a way that does not reveal the manufacturer or brand name if the manufacturer will otherwise not disclose the information to FDA. The fact that information is voluntarily submitted, however, will not in any way inhibit the Food and Drug Administration from taking whatever regulatory action may be warranted under the circumstances. Information of this type submitted in the past will routinely be disclosed to the public upon request unless it contains confidential information or has been received pursuant to a pledge of confidentiality or unless the person submitting it sends to the Food and Drug Administration within 180 days from the effective date of the regulation in this matter a statement justifying why the information should be retained as confidential.

13. All correspondence or summaries of discussions with members of the public, members of Congress, company officials, or other persons who are not Government employees or special Government employees shall be publicly available unless it contains confidential information or constitutes part of an investigatory file for law enforcement purposes.

14. Data and information otherwise not available for public disclosure may be disclosed to Food and Drug Administration consultants, advisory committees, and other persons who are special Government employees. Such persons are thereafter subject to the same laws and regulations with respect to disclosure of such data and information as any other FDA employee.

FDA has at times received broad requests for information which would require deployment of many man-hours to conduct the necessary search, to delete exempt information, to copy the information, and otherwise to process the request.