

§ 4.25 Trade secrets and confidential data or information.

(a) Data and information which are submitted to the Food and Drug Administration or contained in any records of the Food and Drug Administration and which constitute trade secrets or which are confidential are not available for public disclosure. Such data and information will be deleted from any documents that are otherwise available for public disclosure before they are furnished to the public.

(b) A trade secret may consist of any formula, pattern, device, or compilation of information which is used in one's business and which gives them an opportunity to obtain an advantage over competitors who do not know or use it.

(c) Confidential data or information includes trade secrets and other valuable data or information of a type customarily held in strict confidence or regarded as privileged and not disclosed to the public by the person to whom it belongs.

§ 4.26 Data and information submitted voluntarily.

(a) Data and information submitted voluntarily to the Food and Drug Administration and not as a part of any petition, application, or other required submission or request for action are not available for public disclosure if clearly marked as confidential, good cause is shown to justify confidentiality, and the Food and Drug Administration accepts it on this basis. Whenever data or information are submitted voluntarily to the Food and Drug Administration and are marked confidential, a decision will be made prior to acceptance concerning whether it will be accepted on this basis. Applying the guidelines in this section and in Subpart B of Part 4, the director of the bureau to which the data or information is submitted will make the initial determination on whether good cause has been shown to justify confidentiality of the material. If the director concludes that good cause has not been shown, the person submitting the material will be so informed and may appeal this decision to the Assistant Commissioner for Public Affairs whose decision on the matter will be final. If the final decision is that the data or information is not confidential and thus is available for public disclosure, the person will have the opportunity either not to make the submission or to submit it as not confidential.

(b) Safety, effectiveness, and functionality data and information for a developmental or marketed product are available for public disclosure unless the person submitting the data or information refuses to submit it except on a confidential basis.

(c) A protocol for a test or study is available for public disclosure unless it is adequately shown to constitute 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.

(d) Manufacturing methods or processes, including quality control procedures, are not available for public disclosure except to the extent previously disclosed to the public.

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

(f) Adverse reaction and complaint data and information and product experience reports with the names of individuals deleted (including the name of the person using the product and the person reporting the information) are available for public disclosure unless the person submitting the data or information information, and reports which are received on a confidential basis will be available for public disclosure with the names of individuals deleted (including the person using the product and the person reporting the information). The names of manufacturers or product brand names will not be deleted prior to public disclosure unless the person submitting the data or information refuses to submit it except on that condition.

(g) 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.

(h) Every person who has voluntarily submitted data or information to the Food and Drug Administration prior to the effective date of this section may