

submit in writing, within 180 days after such effective date, a request that specified data and information which are contained in the submission(s) and which will otherwise be available for public disclosure in accordance with the principles established in this section shall be retained as confidential and exempt from public disclosure. This request must be accompanied by a statement justifying confidentiality. Any such data and information for which confidentiality is not requested or which the Food and Drug Administration concludes (in accordance with paragraph (a) of this section) are not exempt from public disclosure will be available for public disclosure at the end of this 180-day period. The Food and Drug Administration may defer ruling upon such a request for confidentiality of specified data or information until a request for public disclosure of that data or information is received. In special cases where requests for public disclosure of documents are pending, the Food and Drug Administration may ask for an expedited submission on this matter.

(i) Data and information that may be required to be submitted to the Food and Drug Administration but that are submitted voluntarily instead are not subject to the provisions of this section and will be handled as if they had been required to be submitted.

§ 4.27 Intra-agency and interagency memoranda.

(a) Intra-agency and interagency memoranda which would not be available by law to a private party in litigation with the agency are not available for public disclosure.

(b) Factual information contained in intra-agency or interagency memoranda that are otherwise exempt from public disclosure are available for public disclosure.

§ 4.28 Data and information previously made available to the public.

All data and information contained in Food and Drug Administration files that have in any way previously been furnished to anyone other than an employee or paid consultant in an authorized manner by any person will not be retained by the Food and Drug Administration as confidential unless extraordinary circumstances are shown. Any data or information submitted to the Food and Drug Administration that is requested to be retained as confidential must be accompanied by a statement that the information has not previously been published or furnished to anyone other than an employee or paid consultant. Any such statement is subject to the False Report to the Government Act, 18 U.S.C. 1001.

§ 4.29 Disclosure in administrative or court proceedings.

Data and information otherwise exempt from public disclosure may be revealed in Food and Drug Administration administrative or court proceedings where the data or information are relevant. The Food and Drug Administration will request that the data or information be held in camera and that any other appropriate measures be taken to reduce public disclosure to the minimum necessary under the circumstances.

§ 4.30 Disclosure to consultants and advisory committees.

Data and information otherwise exempt from public disclosure may be disclosed to Food and Drug Administration administrative consultants, advisory committees, and other special Government employees. Such persons are thereafter subject to the same restrictions with respect to the disclosure of such data and information as any other Food and Drug Administration employee.

§ 4.31 Disclosure of identity of individuals.

(a) The names of individuals submitting data or information to the Food and Drug Administration (including the names of consumers who write the Food and Drug Administration) are available for public disclosure unless a request for confidentiality is included or clearly implied. Any such request for confidentiality with respect to the name, address, or other identifying characteristic of an individual will be honored, but requests for confidentiality of corporate names will not be honored unless extraordinary circumstances are shown.

(b) The names or other identifying characteristics of individuals participating as patients or research subjects in any test, study, or other research project will be deleted before the data or information with respect to such test or study are disclosed to the public. Such names or other identifying characteristics should be replaced by a coded means of identification prior to making any such