(g) All safety and effectiveness data and information contained in an IND file which has been discontinued or terminated or contained in a Form 5 file for which the Food and Drug Administration has withdrawn approval for any reason will be available for public disclosure unless extraordinary circumstances are shown.

(h) Adverse reaction data and information are available for public disclosure with the names and other identifying information of individuals deleted (including the person using the product and the person reporting the information).

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

(j) 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.

(k) Every person who has filed an IND or any form pursuant to §146.13 or § 146.14 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 safety, effectiveness, protocol, or assay 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 shall 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 (c) of this section) are not exempt from public disclosure, will be made available to the public at the end of this 180-day period. An extension of the 180-day period will be granted upon a showing that the volume of prior submissions precludes completion of this job within that time and will be conditioned upon prompt filing of all requests for confidentiality as they are completed. 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 cases where public requests for information are pending, the Food and Drug Administration may ask for an expedited submission on this matter.

PART 191—HAZARDOUS SUBSTANCES: DEFINITIONS AND PROCEDURAL AND INTERPRETATIVE REGULATIONS

9. In Part 191, by adding a new paragraph (d) to § 191.213, as follows:

§ 191.213 Presentation of views under section 7 of the act.

* * * * * * *

(d) The documents relating to this proceeding constitute an investigatory file for law enforcement purposes and may include interagency and intra-agency memoranda. No data or information contained in this file are available for public disclosure prior to the file's being closed or the statute of limitations' running, whichever occurs first. After the file is closed or the statute of limitations runs, the factual information contained in the file will be made available for public disclosure except that opinions, policy recommendations, interagency and intra-agency memoranda, statements of witnesses obtained through promises of confidentiality, names of individuals, trade secrets, and other confidential information will be deleted.

Interested persons may, within 60 days after publication hereof in the Federal Register, file with the Hearing Clerk, department of Health, Education, and Welfare, Room 6–88, 5600 Fishers Lane, Rockville, Maryland 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: May 1, 1972.

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.

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