Fees paid to FDA for searching and copying may not be used by FDA to employ persons to conduct the agency's public information program, because they are paid to the U.S. Treasury. The Freedom of Information Act was not intended by Congress to require FDA to divert a major portion of its scarce manpower for conducting such searches and processing rather than in enforcing the important consumer safety laws within its jurisdiction. Accordingly, broad or general requests for information (without at least a minimal description of the documents desired) or for large numbers of documents will be processed taking into account the man-hours required, the tasks from which these resources must be diverted, the impact that this diversion will have upon the Agency's consumer protection activities, and the public policy reasons justifying the request.

Requests are also frequently received to waive the payment of fees. FDA will honor such requests when there is an adequate showing of indigence and when the request has a strong public interest justification. Except under these circumstances, FDA will not discriminate in favor of any person who requests a document by granting an exemption from the payment of costs.

The purpose of this notice is to propose comprehensive rules designed to provide, so far as possible, clear and unambiguous guidelines with respect to the voluminous documents contained in FDA files that are and are not available for public disclosure. Although it is not possible to state with particularity the status of every type of document, it is hoped that the regulations will provide both those who submit information to the Food and Drug Administration and those who seek information from the Food and Drug Administration sufficient guidance to understand what documents will and will not be kept confidential. Specific comment is therefore requested as to whether additional categories of documents should be explicitly covered in the regulations or whether clarification of any of the proposed regulations set out below is advisable.

Paragraphs 8 and 11 of Appendix A to 45 CFR Part 5 contain examples of kinds of FDA records not available for public disclosure. These paragraphs will be revised to reflect the new policy when a final regulation is promulgated in this matter.

Accordingly, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 201 et seq., 52 Stat. 1040 et seq. as amended; 21 U.S.C. 321 et seq.), the Federal Hazardous Substances Act (sec. 1 et seq., 74 Stat. 372 et seq. as amended; 15 U.S.C. 1261 et seq.), the Public Health Service Act (sec. 1, et seq., 58 Stat. 682 et seq. as amended; 42 U.S.C. 201 et seq.), and the Public Information Act (Public Law 89–487 as codified by Public Law 90–23, 81 Stat. 54; 5 U.S.C. 552) and under authority delegated to him (21 CFR 2.120), the Commissioner proposes that Parts 1, 2, 4, 8, 121, 130, 135, 146, and 191 be amended:

PART 1—REGULATIONS FOR THE ENFORCEMENT OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND THE FAIR PACKAGING AND LABELING ACT

1. In Part 1, by adding a new paragraph (c) to § 1.6, as follows:

§ 1.6 Presentation of views under section 305 of the act.

* * * * * * *

(c) 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.

PART 2—ADMINISTRATIVE FUNCTIONS, PRACTICES, AND PROCEDURES

Subpart G—Public Information

2. In Part 2, by deleting Subpart G—Public Information containing § 2.115 *Fee schedule for searching, supplying, and certifying records.* Concurrently, the information in this subpart is being recodified into Part 4 as § 4.20.