turing of a product for shipment solely to such manufacturer only to the extent that the names of such persons and places are registered with the Commissioner of Food and Drugs and he finds upon application of such manufacturer, that (a) the product is in short supply due either to the peculiar growth requirements of the organism involved or to the scarcity of the animal required for manufacturing purposes, and (b) such manufacturer has established with respect to such persons and places such procedures, inspections, tests or other arrangements as will assure full compliance with the applicable regulations of this subchapter related to continued safety, purity, and potency. Such persons and places shall be subject to all regulations of this subchapter except §§ 601.1 to 601.6, 601.9, 601.10, 601.20, 601.21, 601.30 to 601.33, and 610.60 to 610.65 of this chapter. Failure of such manufacturer to maintain such procedures, inspections, tests, or other arrangements, or failure of any person conducting such partial manufacturing to comply with applicable regulations shall constitute a ground for suspension or revocation of the authority conferred pursuant to this section on the same basis as provided in §§ 601.6 to 601.8 with respect to the suspension and the revocation of licenses.

§§ 601.40, 601.41, 601.42, 601.43, 601.44 [Revoked].

54. By revoking §§ 601.40 through 601.44.

PART 701—COSMETIC LABELING

55. In Part 701, by revising § 701.3 (b) and (c) to read as follows:

§ 701.3 Designation of ingredients.

* * * * *

(b) The declaration of ingredients shall appear with such prominence and conspicuousness as to render it likely to be read and understood by ordinary individuals under normal conditions of purchase. The declaration shall appear on any appropriate information panel in letters not less than 1/16 of an inch in height and without obscuring design, vignettes, or crowding. In the absence of sufficient space for such declaration on the package, or where the manufacturer or distributor wishes to use a decorative container, the declaration may appear on a firmly affixed tag, tape, or card. In those cases where there is insufficient space for such declaration on the package, and it is not practical to firmly affix a tag, tape, or card, the Commissioner may establish by regulation an acceptable alternate, e.g., a smaller type size. A petition requesting such a regulation as an amendment to this paragraph shall be submitted pursuant to Part 2 of this chapter.

* * * * *

(e) Interested persons may submit a petition requesting the establishment of a specific name for a cosmetic ingredient pursuant to Part 2 of this chapter. The Commissioner may also propose such a name on his own initiative.

PART 1003—NOTIFICATION OF DEFECTS OF FAILURE TO COMPLY

56. In Part 1003, by amending § 1003.11 by adding an undesignated paragraph at the end of paragraph (a) as follows:

§ 1003.11 Determination by Secretary that product fails to comply or has a defect.

(a) * * *

The manufacturer shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to Subpart F of Part 2 of this chapter.

* * * * *

57. By adding § 1003.31(d) to read as follows:

§ 1003.31 Granting the exemption.

* * * * *

(d) Any person who contests denial of an exemption shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to Subpart F of Part 2 of this chapter.

PART 1004—REPURCHASE, REPAIRS, OR REPLACEMENT OF ELECTRONIC PRODUCTS

58. In Part 1004, by amending § 1004.6 by adding the following new sentence at the end, as follows:

§ 1004.6 Approval of plans.

* * * Any person who contests denial of a plan shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to Subpart F of Part 2 of this chapter.

PART 1210—REGULATIONS UNDER THE FEDERAL IMPORT MILK ACT

59. In Part 1210, by revising the heading of Subpart D and § 1210.30 to read as follows:

Subpart D—Hearings

§ 1210.30 Hearing procedure for permit denial, suspension, and revocation.

Any person who contests denial, suspension, or revocation of a permit shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to Subpart F of Part 2 of this chapter.

60. By revoking § 1210.31 and by redesignating § 1210.63 as new § 1210.31 to read as follows:

§ 1210.31 Hearing before prosecution.

Before violation of the act is referred to the Department of Justice for prosecution under section 5 of the Federal Import Milk Act, an opportunity to be heard will be given to the party against whom prosecution is under consideration. The hearing will be private and confined to questions of fact. The party notified may present evidence, either oral or written, in person or by attorney, to show cause why he should not be prosecuted. After a hearing is held, if it appears that the law has been violated, the facts will be reported to the Department of Justice.

§§ 1210.32, 1210.33, 1210.40, 1210.41, 1210.42, 1210.43, 1210.44, 1210.50, 1210.51, 1210.52, 1210.53, 1210.54, 1210.55, 1210.56, 1210.57, 1210.58, 1210.59, 1210.60, 1210.61, 1210.62, [Revoked].

61. By revoking §§ 1210.32, 1210.33, and Subparts E, F and G of Part 1210, including 1210.40, 1210.41, 1210.42, 1210.43, 1210.44, 1210.50, 1210.51, 1210.52, 1210.53, 1210.54, 1210.55, 1210.56, 1210.57, 1210.58, 1210.59, 1210.60, 1210.61, 1210.62.

Interested persons may, on or before (insert date 30 days after date of publication in the FEDERAL REGISTER), submit to the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852, written comments regarding this proposal. Comments should be filed in quintuplicate (except that individuals may submit single copies), and should be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office Monday through Friday, from 9 a.m. to 4 p.m., except on Federal legal holidays.

Dated: August 29, 1975.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.75-23409 Filed 9-2-75;8:45 am]

federal register

WEDNESDAY, SEPTEMBER 3, 1975



PART IV:

PRIVACY ACT OF 1974

■

VARIOUS AGENCIES

Proposed Rules and Notices of Systems of Records

Title 16—Commercial Practices

CHAPTER I—FEDERAL TRADE COMMISSION

SUBCHAPTER A—PROCEDURES AND RULES OF PRACTICE

PART 4—MISCELLANEOUS RULES

Implementation of Privacy Act Regulations

The Commission announces the following rules, which are effective on October 3, 1975, to implement the Privacy Act of 1974 (Pub. L. 93-579, 5 U.S.C. 552a). The Commission's proposed rules, which were promulgated on August 14, 1975 (40 FR 34162), are amended by these rules. The only changes made have been renumbering the rules and clarifying that all requests under § 4.13 (c) (formerly § 4.13.3) must name the system of records which is the subject of the request and must include any additional information specified in the pertinent system notice as necessary to locate the records requested. Other than correction of typographical errors, no other changes have been made.

Section 4.13 is added to read as follows:

§ 4.13 Privacy Act rules.

(a) *Purpose and Scope*—(1) This section is promulgated to implement the Privacy Act of 1974 (Pub. L. 93-579, 5 U.S.C. 552a) by establishing procedures whereby an individual can, as to all systems of records maintained by the Commission except those set forth in § 4.13(m) as exempt from disclosure, (i) request notification of whether the Commission maintains a record pertaining to him in any system of records, (ii) request access to such a record or to an accounting of its disclosure, (iii) request that the record be amended or corrected, and (iv) appeal an initial adverse determination of any such request. This section also establishes those systems of records that are specifically exempt from disclosure and from other requirements.

(2) The procedures of this section apply only to requests by an individual as defined in § 4.13(b). Except as otherwise provided, they govern only records containing personal information in systems of records for which notice has been published by the Commission in the FEDERAL REGISTER pursuant to section 552a(e)(4) of the Privacy Act of 1974 and which are neither exempt from the provisions of this section nor contained in government-wide systems of personnel records for which notice has been published in the FEDERAL REGISTER by the Civil Service Commission. Requests for notification, access, and amendment of personnel records which are contained in a system of records for which notice has been given by the Civil Service Commission are governed by the Civil Service Commission's notices, 5 CFR Part 297. Access to records which are not subject to the requirements of the Privacy Act are governed by §§ 4.8-4.11.

(b) *Definitions.*—The following definitions apply to this section only:

(1) "Individual" means a natural person who is a citizen of the United States or an alien lawfully admitted for permanent residence.

(2) "Record" means any item, collection, or grouping of personal information about an individual that is maintained by the Commission, including, but not limited to, his education, financial transactions, medical history, and criminal or employment history and that contains his name, or the identifying number, symbol, or other identifying particular assigned to the individual, such as a finger or voice print or a photograph, but does not include information concerning proprietorships, businesses, or corporations.

(3) "System of records" means a group of any records under the control of the Commission from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual, for which notice has been published by the Commission in the FEDERAL REGISTER pursuant to 5 U.S.C. 552a(e)(4).

(c) *Procedures for requests pertaining to individual records in a record system.*—An individual may request access to his records or any information pertaining to him in a system of records, and notification of whether and to whom the Commission has disclosed a record for which an accounting of disclosures is required to be kept and made available to him, using the procedures of this subsection. Requests for the disclosure of records under this subsection or to determine whether a system of records contains records pertaining to an individual or to obtain an accounting of disclosures, shall be in writing and if mailed, addressed as follows:

Privacy Act Request, Office of the Secretary, Federal Trade Commission, 6th Street and Pennsylvania Avenue NW., Washington, D.C. 20580.

If requests are presented in person at the Office of the Secretary, the individual shall be required to execute a written request. All requests must name the system of records which is the subject of the request, and must include any additional information specified in the pertinent system notice as necessary to locate the records requested. If the requester desires to permit a person to accompany him to review his record, the request shall so state. Nothing in this section shall allow an individual access to any information compiled in reasonable anticipation of a civil action or proceeding.

(d) *Times, places, and requirements for identification of individuals making requests.*—Verification of identity of persons making written requests to the Secretary ordinarily will not be required. The signature upon such requests shall be deemed to be a certification by the person signing that he is the individual to whom the record pertains or the parent of a minor or the duly appointed legal guardian of the individual to whom the record pertains. The Secretary may require additional verification of identity as specified by him when necessary reasonably to assure that records are not improperly disclosed; provided, however, that no verification of identity will be required where the records sought are publicly available under the Freedom of Information Act.

(e) *Disclosure of requested information to individuals.*—Within ten (10) working days of receipt of a request under § 4.13 (c), the Secretary shall acknowledge receipt of the request. Within thirty (30) working days of the receipt of a request under § 4.13(c), the Secretary shall inform the requester whether a system of records containing retrievable information pertaining to the requester exists, and if so, either that his request has been granted or that the requested records or information is exempt from disclosure pursuant to § 4.13(m). When, for good cause shown, the Secretary is unable to respond within thirty (30) working days of the receipt of the request, he shall notify the requester of that fact and approximately when it is anticipated that a response will be made.

(f) *Special procedures: Medical records.*—When the Secretary determines that disclosure of a medical or psychological record directly to a requesting individual could have an adverse effect on the individual, he shall require the individual to designate a medical doctor to whom the record will be transmitted.

(g) *Request for correction or amendment of record.*—An individual to whom access to his records or any information pertaining to him in a system of records has been granted may request that any portion thereof be amended or corrected because he believes it is not accurate, relevant, timely, or complete. An initial request for correction or amendment of a record shall be in writing whether presented in person or by mail, and if by mail, addressed as in § 4.13(c). In making a request under this subsection, the requesting party shall state the nature of the information in the record the individual believes to be inaccurate, irrelevant, untimely, or incomplete, the correction or amendment desired, and the reasons therefore.

(h) *Agency review of request for correction or amendment of record.*—Whether presented in person or by mail, requests under § 4.13(g) shall be acknowledged by the Secretary within ten (10) working days of the receipt of the request if action on the request cannot be completed and the individual notified of the results within that time. Thereafter, the Secretary shall promptly either make the requested amendment or correction or inform the requester of his refusal to make the amendment or correction, the reasons for the refusal, and the requester's right to appeal that determination in accordance with § 4.13 (i).

(i) *Appeal of initial adverse agency determination.*—(1) If the Secretary denies an initial request under § 4.13(c) or § 4.13(g), the requester may appeal that determination to the Commission. The appeal shall be in writing and addressed as follows:

Privacy Act Appeal, Office of the General Counsel, Federal Trade Commission, 6th Street and Pennsylvania Avenue NW., Washington, D.C. 20580.

The Commission shall notify the requester within thirty (30) working days of the receipt of his appeal of the disposition of that appeal, except that the thirty (30) day period may be extended for good cause, in which case the requester will be advised of the approximate date on which review will be completed.

(2) (i) If the Commission refuses to amend or correct the record in accordance with a request under § 4.13(g), it shall notify the requester of that determination and inform him of his right to file with the Secretary of the Commission a concise statement setting forth the reasons for his disagreement with that determination and the fact that such a statement will be treated as set forth in subparagraph (ii). The Commission shall also inform the requester that judicial review of the determination is available by a civil suit in the district in which the requester resides, or has his principal place of business, or in which the agency records are situated, or in the District of Columbia.

(ii) If the individual files a statement disagreeing with the Commission's determination not to amend or correct a record, it shall be clearly noted in the record involved and made available to anyone to whom the record has been disclosed after September 27, 1975, or is subsequently disclosed together with, if the Commission deems it appropriate, a brief statement of the reasons for refusing to amend the record.

(j) *Disclosure of record to person other than the individual to whom it pertains.*—Except as provided by 5 U.S.C. 552a(b), the written request or prior written consent of the individual to whom a record pertains, or of his parent if a minor, or legal guardian if incompetent, shall be required before such record is disclosed. If the individual elects to inspect a record in person and desires to be accompanied by another person, the Secretary may require the individual to furnish a signed statement authorizing his record to be disclosed in the presence of the accompanying named person.

(k) *Fees.*—No fees shall be charged for searching for a record, reviewing it, or for copies of records made by the Commission for its own purposes incident to granting access to a requester. Copies of records to which access has been granted under this section may be obtained by the requester from the Secretary upon payment of the reproduction fees provided in § 4.8(c)(2).

(l) *Penalties.* Section 552a(i)(3) of the Privacy Act, 5 U.S.C. 552a(i)(3), makes it a misdemeanor, subject to a maximum fine of $5,000, to knowingly and willfully request or obtain any record concerning an individual under false pretenses. Sections 552a(i) (1) and (2) of the Privacy Act, 5 U.S.C. 552a(i) (1) and (2), provide penalties for violations by agency employees of the Privacy Act or regulations established thereunder. Title 18 U.S.C. 1001, Crimes and Criminal Procedures, makes it a criminal offense, subject to a maximum fine of $10,000 or imprisonment for not more than 5 years or both, to knowingly and willfully make or cause to be made any false or fraudulent statements or representations in any matter within the jurisdiction of any agency of the United States.

(m) *Specific exemptions.*—Pursuant to 5 U.S.C. § 552a(k)(2), investigatory material compiled for law enforcement purposes in the following systems of records is exempt from subsections (c)(3), (d), (e)(1), (e)(4) (G), (H), and (I), and (f) of 5 U.S.C. 552a, and from the provisions of this section, except as otherwise provided in § 552a(k)(2):

Disciplinary Action Investigatory Files—FTC.
Investigational, Legal, and Public Records—FTC.
Litigation Information Management Systems for Investigations, Rulemaking, and Adjudicatory Proceedings—FTC.
Preliminary Investigation Files—FTC.

Issued by direction of the Commission dated August 27, 1975.

CHARLES A. TOBIN,
Secretary.

[FR Doc.75-23270 Filed 9-2-75;8:45 am]