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National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22162, which reproduces and distributes such information to the public at cost. A single copy of each such record shall be available for public review at the Food and Drug Administration. All persons requesting copies of such records shall be answered by referring the person requesting the records to NTIS.

[42 FR 15616, Mar. 22, 1977, as amended at 54 FR 9038, Mar. 3, 1989. Redesignated at 68 FR 25286, May 12, 2003]

§ 20.53 Use of private contractor for copying.

The Food and Drug Administration may furnish requested records to a private contractor for copying after deletion of all nondisclosable data and information. Under these circumstances, the Food and Drug Administration will charge the person requesting the records for all of the fees involved pursuant to § 20.45.

[42 FR 15616, Mar. 22, 1977. Redesignated and amended at 68 FR 25286, 25287, May 12, 2003]

§ 20.54 Request for review without copying.

(a) A person requesting disclosure of records shall be permitted an opportunity to review them without the necessity for copying them where the records involved contain only disclosable data and information. Under these circumstances, the Food and Drug Administration will charge only for the costs of searching for the records.

(b) Where a request is made for review of records without copying, and the records involved contain both disclosable and nondisclosable information, the records containing nondisclosable information shall first be copied with the nondisclosable information blocked out and the Food and Drug Administration will charge for the costs of searching and copying.

[42 FR 15616, Mar. 22, 1977. Redesignated at 68 FR 25286, May 12, 2003]

§ 20.55 Indexing trade secrets and confidential commercial or financial information.

Whenever the Food and Drug Administration denies a request for a record or portion thereof on the grounds that the record or portion thereof is exempt from public disclosure as trade secret or confidential commercial or financial data and information under § 20.61, and the person requesting the record subsequently contests the denial in the courts, the Food and Drug Administration will so inform the person affected, i.e., the person who submitted the record, and will require that such person intervene to defend the exempt status of the record. If a court requires the Food and Drug Administration to itemize and index such records, the Food and Drug Administration will so inform the person affected and will require that such person undertake the itemization and indexing of the records. If the affected person fails to intervene to defend the exempt status of the records and to itemize and index the disputed records, the Food and Drug Administration will take this failure into consideration in deciding whether that person has waived such exemption so as to require the Food and Drug Administration to promptly make the records available for public disclosure.

[42 FR 15616, Mar. 22, 1977, as amended at 59 FR 535, Jan. 5, 1994. Redesignated at 68 FR 25286, May 12, 2003]

Subpart D—Exemptions

§ 20.60 Applicability of exemptions.

(a) The exemptions established in this subpart shall apply to all Food and Drug Administration records, except as provided in subpart E of this part. Accordingly, a record that is ordinarily available for public disclosure in accordance with the provisions in subpart F of this part or of another regulation cross-referenced in § 20.100(c) is not available for such disclosure to the extent that it falls within an exemption contained in this subpart, except as provided by the limitations on exemptions specified in subpart E of this part. For example, correspondence that is ordinarily disclosable under § 20.103