

§ 20.50

(c) A letter denying a request for records, in whole or in part, shall state the reasons for the denial and shall state that an appeal may be made to the Deputy Assistant Secretary for Public Affairs (Media), Department of Health and Human Services. The agency will also make a reasonable effort to include in the letter an estimate of the volume of the records denied, unless providing such an estimate would harm an interest protected by an exemption under the Freedom of Information Act. This estimate will ordinarily be provided in terms of the approximate number of pages or some other reasonable measure. This estimate will not be provided if the volume of records denied is otherwise indicated through deletions on records disclosed in part.

(d) Minor deletions of nondisclosable data and information from disclosable records shall not be deemed to be a denial of a request for records.

[42 FR 15616, Mar. 22, 1977, as amended at 46 FR 8457, Jan. 27, 1981; 55 FR 1405, Jan. 16, 1990. Redesignated and amended at 68 FR 25286, 25287, May 12, 2003]

§ 20.50 Nonspecific and overly burdensome requests.

The Food and Drug Administration will make every reasonable effort to comply fully with all requests for disclosure of nonexempt records. Nonspecific requests or requests for a large number of documents that require the deployment of a substantial amount of agency man-hours to search for and compile will be processed taking into account the staff-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 requests. A decision on the processing of such a request for information shall be made after balancing the public benefit to be gained by the disclosure against the public loss that will result from diverting agency personnel from their other responsibilities. In any situation in which it is determined that a request for voluminous records would unduly burden and interfere with the operations of the Food and Drug Administration, the person making the request will be asked to be more specific

21 CFR Ch. I (4-1-04 Edition)

and to narrow the request, and to agree on an orderly procedure for the production of the requested records, in order to satisfy the request without disproportionate adverse effects on agency operations.

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

§ 20.51 Referral to primary source of records.

Upon receipt of a request for a record or document which is contained in Food and Drug Administration files but which is available elsewhere at a lower cost, the person requesting the record or document shall be referred to the primary source of the record or document.

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

§ 20.52 Availability of records at National Technical Information Service.

The Food and Drug Administration is furnishing a number of records to the 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]