section, the Food and Drug Administra-
tion will normally waive fees. How-
ever, in some cases the Food and Drug Administration may decide only to re-
duce the fees. For example, the Food and Drug Administration may do this when disclosure of some but not all of the requested records passes the tests.

(c) Procedure for requesting a waiver or reduction. A requester must request a waiver or reduction of fees at the same time as the request for records. The re-
quester should explain why a waiver or reduction is proper under the factors set forth in paragraphs (a) through (d) of this section. Only the Associate Commissioner for Public Affairs may make the decision whether to waive or reduce the fees. If the Food and Drug Administration does not completely grant the request for a waiver or reduc-
tion, the denial letter will designate a review official. The requester may ap-
peal the denial to that official. The appeal letter should address reasons for the Associate Commissioner’s decision that are set forth in the denial letter.


§ 20.47 Situations in which confiden-
tiality is uncertain.

In situations where the confiden-
tiality of data or information is uncer-
tain and there is a request for public disclosure, the Food and Drug Administra-
tion will consult with the person who has submitted or divulged the data or information or who would be af-
fected by disclosure before determining whether or not such data or informa-
tion is available for public disclosure.


§ 20.48 Judicial review of proposed disclosure.

Where the Food and Drug Administra-
tion consults with a person who will be affected by a proposed disclosure of data or information contained in Food and Drug Administration records pur-
suant to § 20.47, and rejects the person’s request that part or all of the records not be made available for public disclo-
sure, the decision constitutes final agency action that is subject to judi-
cial review pursuant to 5 U.S.C. chapter 7. The person affected will be per-
mittet 5 days after receipt of notifica-
tion of such decision within which to institute suit in a United States Dis-
trict Court to enjoin release of the records involved. If suit is brought, the Food and Drug Administration will not disclose the records involved until the matter and all related appeals have been concluded.


§ 20.49 Denial of a request for records.

(a) A denial of a request for records, in whole or in part, shall be signed by the Assistant Commissioner for Public Affairs (or delegatee).

(b) The name and title or position of each person who participated in the de-

(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 agen-
cy 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 reason-
able measure. This estimate will not be provided if the volume of records de-

(d) Minor deletions of nondisclosable data and information from disclosable records shall not be deemed to be a de-

§ 20.50 Nonspecific and overly burden-
some requests.

The Food and Drug Administration will make every reasonable effort to