Food and Drug Administration, HHS

§ 20.104 Summaries of oral discussions.
(a) All written summaries of oral discussions, whether in person or by tele
phone, with members of the public, members of Congress, organization or
company officials, or other persons, except members of the Executive Branch
of the Federal government or special government employees, are available
for public disclosure.
(b) Any such summary is available for public disclosure at the time that it
is prepared by the Food and Drug Administration unless a different time for
such disclosure is specified in other rules established or cross-referenced in
this part, e.g., summaries of oral discussions relating to a food additive pe-
tition in §171.1(h)(3) of this chapter.
(c) If more than one summary of an oral discussion exists in a Food and
Drug Administration file, all such summaries shall be disclosed in response to
any request for such summary.

§ 20.105 Testing and research con-
ducted by or with funds provided
by the Food and Drug Administra-
tion.
(a) Any list that may be prepared by
the Food and Drug Administration of
testing and research being conducted
by or with funds provided by the Food
and Drug Administration is available
for public disclosure.
(b) Any contract relating to agency
testing and research, and any progress
report relating thereto, is available for
public disclosure.
(c) The results of all testing or re-
search conducted by or with funds pro-
vided by the Food and Drug Adminis-
tration, such as toxicological testing,
compliance assays, methodology stud-
ies, and product testing, are available
for public disclosure when the final re-
port is complete and accepted by the
responsible Food and Drug Administra-
tion official, after deletion of any in-
formation that would reveal confiden-
tial investigative techniques and pro-
cedures, e.g., the use of “markers” to
document adulteration of a product. If
such results are disclosed in an author-
ized manner to any member of the pub-
lic before the final report is available,
they are immediately available for
public disclosure to any member of the
public who requests them.
(d) Access to all raw data, slides,
worksheets, and other similar working
materials shall be provided at the same
time that the final report is disclosed.

§ 20.106 Studies and reports prepared
by or with funds provided by the
Food and Drug Administration.
(a) The following types of reports and
studies prepared by or with funds pro-
vided by the Food and Drug Adminis-
tration are available for public disclo-
ure upon their acceptance by the re-
sponsible agency official:
(1) Quarterly and annual reports of
the agency.
(2) External investigations or review
of agency needs and performance.
(3) Surveys, compilations, and sum-
maries of data and information.
(4) Consumer surveys.
(5) Compliance surveys.
(6) Compliance programs, except that
names of specific firms, the location of
specific activities, and details about
sampling numbers or sizes shall be de-
leted until implementation of the pro-
gram is completed.
(7) Work plans prepared by Food and
Drug Administration centers, field of-
fices, and other components, except
that names of specific firms, the loca-
tion of specific activities, and details
about sampling numbers or sizes shall be de-
leted until implementation of the plan is com-
pleted.
(b) The following types of reports and
studies prepared by or with funds pro-
vided by the Food and Drug Adminis-
tration are not available for public dis-
closure:
(1) Internal audits of agency needs
and performance.
(2) Records relating to the internal
planning and budget process.
(3) Legislative proposals or com-
ments prior to submission to Congress.
[42 FR FR 15616, Mar. 22, 1977, as amended at
50 FR 8995, Mar. 6, 1985]

§ 20.107 Food and Drug Administra-
tion manuals.
(a) Food and Drug Administration
administrative staff manuals and in-
stuctions that affect a member of the
public are available for public disclo-
sure. An index of all such manuals is
available by writing to the Freedom of
Information Staff (HFI–35), Food and
§ 20.108 Agreements between the Food and Drug Administration and other departments, agencies, and organizations.

(a) All written agreements and understandings signed by the Food and Drug Administration and other departments, agencies, and organizations are available for public disclosure.

(b) A permanent file of all such agreements and understandings is available for public review during working hours in the Food and Drug Administration’s Freedom of Information Public Room.

(c) All such agreements and understandings shall be published in the Federal Register, except those agreements and memoranda of understanding between FDA and State or local government agencies that are cooperative work-sharing agreements. In lieu of publication of the complete text of these agreements and understandings, FDA will publish in the Federal Register periodically, but not less than once every 2 years, a notice listing all such agreements and memoranda of understanding currently in effect between FDA and State or local government agencies.

(d) Agreements and understandings signed by officials of FDA with respect to activities of the Office of Criminal Investigations are exempt from the requirements set forth in paragraphs (b) and (c) of this section. Although such agreements and understandings will not be put on display in FDA’s Freedom of Information Public Room or published in the Federal Register, these agreements will be available for disclosure in response to a request from the public after deletion of information that would disclose confidential investigative techniques or procedures, or information that would disclose guidelines for law enforcement investigations if such disclosure could reasonably be expected to risk circumvention of the law.


§ 20.109 Data and information obtained by contract.

(a) All data and information obtained by the Food and Drug Administration by contract, including all progress reports pursuant to a contract, are available for public disclosure when accepted by the responsible agency official except to the extent that they remain subject to an exemption established in subpart D of this part, e.g., they relate to law enforcement matters as provided in § 20.88(b).

(b) Upon the awarding of a contract by the Food and Drug Administration, the technical proposal submitted by the successful offeror will be available for public disclosure. All cost proposals and the technical proposals of unsuccessful offerors submitted in response to a request for proposals are exempt from disclosure as confidential commercial or financial information pursuant to §20.61.

§ 20.110 Data and information about Food and Drug Administration employees.

(a) The name, title, grade, position description, salary, work address, and work telephone number for every Food