§ 20.104 Summaries of oral discussions.
(a) All written summaries of oral discussions, whether in person or by telephone, 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 petition 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 conducted by or with funds provided by the Food and Drug Administration.
(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 research conducted by or with funds provided by the Food and Drug Administration, such as toxicological testing, compliance assays, methodology studies, and product testing, are available for public disclosure when the final report is complete and accepted by the responsible Food and Drug Administration official, after deletion of any information that would reveal confidential investigative techniques and procedures, e.g., the use of “markers” to document adulteration of a product. If such results are disclosed in an authorized manner to any member of the public 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 provided by the Food and Drug Administration are available for public disclosure upon their acceptance by the responsible agency official:
   (1) Quarterly and annual reports of the agency.
   (2) External investigations or review of agency needs and performance.
   (3) Surveys, compilations, and summaries 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 deleted until implementation of the program is completed.
   (7) Work plans prepared by Food and Drug Administration centers, field offices, and other components, except that names of specific firms, the location of specific activities, and details about sampling numbers or sizes shall be deleted until implementation of the plan is completed.
   (b) The following types of reports and studies prepared by or with funds provided by the Food and Drug Administration are not available for public disclosure:
      (1) Internal audits of agency needs and performance.
      (2) Records relating to the internal planning and budget process.
      (3) Legislative proposals or comments prior to submission to Congress.

§ 20.107 Food and Drug Administration manuals.
(a) Food and Drug Administration administrative staff manuals and instructions that affect a member of the public are available for public disclosure. 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. 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