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(5) Whenever the Food and Drug Administration sends a notice to a submitter under paragraph (e)(1) of this section, the Food and Drug Administration will notify the requester that the Food and Drug Administration is giving the submitter a notice and an opportunity to object. Whenever the Food and Drug Administration sends a notice to a submitter under paragraph (e)(3) of this section, the Food and Drug Administration will notify the requester of this fact.

(f) The notice requirements in paragraph (e) of this section do not apply in the following situations:

(1) The Food and Drug Administration decided not to disclose the records;

(2) The information has previously been published or made generally available;

(3) Disclosure is required by a regulation issued after notice and opportunity for public comment, that specifies narrow categories of records that are to be disclosed under the Freedom of Information Act, but in this case a submitter may still designate records as described in paragraph (d) of this section, and in exceptional cases, the Food and Drug Administration may, at its discretion, follow the notice procedures in paragraph (e) of this section;

(4) The information requested has not been designated by the submitter as exempt from disclosure when the submitter had an opportunity to do so at the time of submission of the information or within a reasonable time thereafter, unless the Food and Drug Administration has substantial reason to believe that disclosure of the information would result in competitive harm; or

(5) The designation appears to be obviously frivolous, but in this case the Food and Drug Administration will still give the submitter the written notice required by paragraph (e)(3) of this section (although this notice need not explain our decision or include a copy of the records), and the Food and Drug Administration will notify the requester as described in paragraph (e)(5) of this section.

[42 FR 15616, Mar. 22, 1977, as amended at 59 FR 535, Jan. 5, 1994; 87 FR 55913, Sept. 13, 2022]

§ 20.62 Inter- or intra-agency memoranda or letters.

Interagency or intra-agency memoranda or letters that would not be available by law to a party other than an agency in litigation with the Food and Drug Administration may be withheld from public disclosure except that factual information that is reasonably segregable in accordance with the rule established in § 20.22 is available for public disclosure. The deliberative process privilege shall not apply to records created 25 years or more before the date on which the records were requested.

[87 FR 55913, Sept. 13, 2022]

§ 20.63 Personnel, medical, and similar files, disclosure of which constitutes a clearly unwarranted invasion of personal privacy.

(a) The names or other information which would identify patients or research subjects in any medical or similar report, test, study, or other research project shall be deleted before the record is made available for public disclosure.

(b) The names and other information which would identify patients or research subjects should be deleted from any record before it is submitted to the Food and Drug Administration. If the Food and Drug Administration subsequently needs the names of such individuals, a separate request will be made.

(c) Requests for deletion of business or product names prior to disclosure of any record to the public shall not be granted on the ground of privacy, but such deletion may be justified under another exemption established in this subpart, e.g., the exemption for trade secrets and confidential commercial or financial information under § 20.61.

(d) Names of individuals conducting investigations, studies, or tests on products or ingredients shall not be deleted prior to disclosure of any record to the public unless extraordinary circumstances are shown.

(e) A request for all records relating to a specific individual will be denied as a clearly unwarranted invasion of personal privacy unless accompanied by the written consent of the individual named.

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(f) The names and any information that would identify the voluntary reporter or any other person associated with an adverse event involving a human drug, biologic, or medical device product shall not be disclosed by the Food and Drug Administration or by a manufacturer in possession of such reports in response to a request, demand, or order. Information that would identify the voluntary reporter or persons identified in the report includes, but is not limited to, the name, address, institution, or any other information that would lead to the identities of the reporter or persons identified in a report. This provision does not affect disclosure of the identities of reporters required by a Federal statute or regulation to make adverse event reports. Disclosure of the identities of such reporters is governed by the applicable Federal statutes and regulations.

(1) *Exceptions.* (i) Identities may be disclosed if both the voluntary reporter and the person identified in an adverse event report or that person's legal representative consent in writing to disclosure, but neither FDA nor any manufacturer in possession of such reports shall be required to seek consent for disclosure from the voluntary reporter or the person identified in the adverse event report or that person's legal representative; or

(ii) Identities of the voluntary reporter and the person who experienced the reported adverse event may be disclosed pursuant to a court order in the course of medical malpractice litigation involving both parties; or (iii) The report, excluding the identities of any other individuals, shall be disclosed to the person who is the subject of the report upon request.

(2) *Preemption.* No State or local governing entity shall establish or continue in effect any law, rule, regulation, or other requirement that permits or requires disclosure of the identities of the voluntary reporter or other person identified in an adverse event report except as provided in this section.

[42 FR 15616, Mar. 22, 1977, as amended at 60 FR 16968, Apr. 3, 1995]

§ 20.64 Records or information compiled for law enforcement purposes.

(a) Records or information compiled for law enforcement purposes may be withheld from public disclosure pursuant to the provisions of this section to the extent that disclosure of such records or information:

(1) Could reasonably be expected to interfere with enforcement proceedings;

(2) Would deprive a person to a right to a fair trial or an impartial adjudication;

(3) Could reasonably be expected to constitute an unwarranted invasion of personal privacy;

(4) Could reasonably be expected to disclose the identity of a confidential source, including a State, local, or foreign agency or authority or any private institution which furnished information on a confidential basis; and information furnished by a confidential source in the case of a record compiled by the Food and Drug Administration or any other criminal law enforcement authority in the course of a criminal investigation or by an agency conducting a lawful national security intelligence investigation;

(5) Would disclose techniques and procedures for law enforcement investigations or prosecutions or would disclose guidelines for law enforcement investigations or prosecutions, if such disclosure could reasonably be expected to risk circumvention of the law; or

(6) Could reasonably be expected to endanger the life or physical safety of any individual.

(b) Records include all records relating to regulatory enforcement action, including both administrative and court action, which have not been disclosed to any member of the public, including any person who is the subject of the investigation.

(c) Any record which is disclosed to any person, including any person who is the subject of a Food and Drug Administration investigation, and any data or information received from any person who is the subject of a Food and Drug Administration investigation relating to such investigation, is available for public disclosure at that time

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