Food and Drug Administration, HHS

§ 20.63

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

All communications within the Executive Branch of the Federal government which are in written form or which are subsequently reduced to writing may be withheld from public disclosure except that factual information which is reasonably segregable in accordance with the rule established in §20.22 is available for public disclosure.

§ 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.

(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

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§ 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;

(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 in accordance with the rule established in §20.21, except that:

(1) Disclosure of such records shall be subject to the other exemptions established in this subpart and to the limitations on exemptions established in subpart E of this part.

(2) The record of a section 305 hearing shall be available for public disclosure only in accordance with the provisions of §7.87 of this chapter.