

and Drug Administration employee are available for public disclosure. The home address and home telephone number of any such employee are not available for public disclosure.

(b) Statistics on the prior employment experience of present agency employees, and subsequent employment of past agency employees, are available for public disclosure.

§ 20.111 Data and information submitted voluntarily to the Food and Drug Administration.

(a) The provisions of this section shall apply only to data and information submitted voluntarily to the Food and Drug Administration, whether in the course of a factory inspection or at any other time, and not as a part of any petition, application, master file, or other required submission or request for action. Data and information that may be required to be submitted to the Food and Drug Administration but that are submitted voluntarily instead are not subject to the provisions of this section and will be handled as if they had been required to be submitted.

(b) A determination that data or information submitted voluntarily will be held in confidence and will not be available for public disclosure shall be made only in the form of a regulation published or cross-referenced in this part.

(c) The following data and information submitted voluntarily to the Food and Drug Administration are available for public disclosure unless extraordinary circumstances are shown:

(1) All safety, effectiveness, and functionality data and information for a marketed ingredient or product, except as provided in § 330.10(a)(2) of this chapter for OTC drugs.

(2) A protocol for a test or study, unless it is shown to fall within the exemption established in § 20.61 for trade secrets and confidential commercial or financial information.

(3) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information shall be disclosed as follows:

(i) If submitted by a consumer or user of the product, the record is available for public disclosure after deletion of names and other information that

would identify the person submitting the information.

(ii) If submitted by the manufacturer of the product, the record is available for public disclosure after deletion of:

(a) Names and any information that would identify the person using the product.

(b) Names and any information that would identify any third party involved with the report, such as a physician or hospital or other institution.

(c) Names and any other information that would identify the manufacturer or the brand designation of the product, but not the type of product or its ingredients.

(iii) If submitted by a third party, such as a physician or hospital or other institution, the record is available for public disclosure after deletion of:

(a) Names and any information that would identify the person using the product.

(b) Names and any information that would identify any third party involved with the report, such as a physician or hospital or other institution.

(iv) If obtained through a Food and Drug Administration investigation, the record shall have the same status as the initial report which led to the investigation, i.e., it shall be disclosed in accordance with paragraph (c)(3)(i) through (iii) of this section.

(v) Any compilation of data, information, and reports prepared in a way that does not reveal data or information which is not available for public disclosure under this section is available for public disclosure.

(vi) If a person requests a copy of any such record relating to a specific individual or a specific incident, such request will be denied unless accompanied by the written consent to such disclosure of the person who submitted the report to the Food and Drug Administration and the individual who is the subject of the report. The record will be disclosed to the individual who is the subject of the report upon request.

(4) A list of all ingredients contained in a food or cosmetic, whether or not it is in descending order of predominance, or a list of all active ingredients and any inactive ingredients previously disclosed to the public as defined in

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§ 20.81 contained in a drug, or a list of all ingredients or components in a device.

(5) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and is shown to fall within the exemption established in § 20.61.

(d) The following data and information submitted voluntarily to the Food and Drug Administration are not available for public disclosure unless they have been previously disclosed to the public as defined in § 20.81 or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in § 20.61:

(1) All safety, effectiveness, and functionality data and information for a developmental ingredient or product that has not previously been disclosed to the public as defined in § 20.81.

(2) Manufacturing methods or processes, including quality control procedures.

(3) Production, sales, distribution, and similar data and information, except that any compilation of such data and information aggregated and prepared in a way that does not reveal data or information which is not available for public disclosure under this provision is available for public disclosure.

(4) Quantitative or semiquantitative formulas.

(e) For purposes of this regulation, safety, effectiveness, and functionality data include all studies and tests of an ingredient or a product on animals and humans and all studies and tests on the ingredient or product for identity, stability, purity, potency, bioavailability, performance, and usefulness.

[42 FR 15616, Mar. 22, 1977, as amended at 68 FR 25287, May 12, 2003]

§ 20.112 Voluntary drug experience reports submitted by physicians and hospitals.

(a) A voluntary drug experience report to the Food and Drug Administration on FDA Form 3500 shall be handled in accordance with the rules established in § 20.111(c)(3)(iii).

(b) If a person requests a copy of any such record relating to a specific indi-

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vidual or a specific incident, such request will be denied unless accompanied by the written consent to such disclosure of the person who submitted the report to the Food and Drug Administration and the individual who is the subject of the report.

[42 FR 15616, Mar. 22, 1977, as amended at 54 FR 9038, Mar. 3, 1989; 62 FR 52249, Oct. 7, 1997]

§ 20.113 Voluntary product defect reports.

Voluntary reports of defects in products subject to the jurisdiction of the Food and Drug Administration are available for public disclosure:

(a) If the report is submitted by the manufacturer, after deletion of data and information falling within the exemptions established in § 20.61 for trade secrets and confidential commercial or financial information and in § 20.63 for personal privacy.

(b) If the report is submitted by any person other than the manufacturer, after deletion of names and other information that would identify the person submitting the report and any data or information falling within the exemption established in § 20.63 for personal privacy.

§ 20.114 Data and information submitted pursuant to cooperative quality assurance agreements.

Data and information submitted to the Food and Drug Administration pursuant to a cooperative quality assurance agreement shall be handled in accordance with the rules established in § 20.111.

§ 20.115 Product codes for manufacturing or sales dates.

Data or information in Food and Drug Administration files which provide a means for deciphering or decoding a manufacturing date or sales date or use date contained on the label or in labeling or otherwise used in connection with a product subject to the jurisdiction of the Food and Drug Administration are available for public disclosure.

§ 20.116 Drug and device listing information.

Information submitted to the Food and Drug Administration pursuant to