in accordance with part 20 of this chapter.

(b) Before public disclosure of a report, FDA will delete from the report:

(1) Any information that constitutes trade secret or confidential commer-
cial or financial information under §20.61 of this chapter; and

(2) Any personnel, medical, or similar information, including the serial num-
bers of implanted devices, which would constitute a clearly unwarranted inva-
sion of personal privacy under §20.63 of this chapter or 5 U.S.C. 552(b)(6); pro-
vided, that except for the information under §20.61 of this chapter or 5 U.S.C.
552(b)(4), FDA will disclose to a patient who requests a report all the informa-
tion in the report concerning that pa-

tient.

PART 807—ESTABLISHMENT REG-
ISTRATION AND DEVICE LISTING
FOR MANUFACTURERS AND INI-
TIAL IMPORTERS OF DEVICES

Subpart A—General Provisions

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ishment registration or to registration
number.

Subpart C—Registration Procedures for
Foreign Device Establishments

807.40 Establishment registration and de-
vice listing for foreign establishments
importing or offering for import devices
into the United States.
required to have an approved premarket approval application as provided in section 515 of the act; or

(4) For foreign establishments, the distribution of any device that is neither imported nor offered for import into the United States.

(c) Establishment means a place of business under one management at one general physical location at which a device is manufactured, assembled, or otherwise processed.

(d) Manufacture, preparation, propagation, compounding, assembly, or processing of a device means the making by chemical, physical, biological, or other procedures of any article that meets the definition of device in section 201(h) of the act. These terms include the following activities:

(1) Repackaging or otherwise changing the container, wrapper, or labeling of any device package in furtherance of the distribution of the device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer;

(2) Initial importation of devices manufactured in foreign establishments; or

(3) Initiation of specifications for devices that are manufactured by a second party for subsequent commercial distribution by the person initiating specifications.

(e) Official correspondent means the person designated by the owner or operator of an establishment as responsible for the following:

(1) The annual registration of the establishment;

(2) Contact with the Food and Drug Administration for device listing;

(3) Maintenance and submission of a current list of officers and directors to the Food and Drug Administration upon the request of the Commissioner;

(4) The receipt of pertinent correspondence from the Food and Drug Administration directed to and involving the owner or operator and/or any of the firm’s establishments; and

(5) The annual certification of medical device reports required by §804.30 of this chapter or forwarding the certification form to the person designated by the firm as responsible for the certification.

(f) Owner or operator means the corporation, subsidiary, affiliated company, partnership, or proprietor directly responsible for the activities of the registering establishment.

(g) Initial importer means any importer who furthers the marketing of a device from a foreign manufacturer to the person who makes the final delivery or sale of the device to the ultimate consumer or user, but does not repackage, or otherwise change the container, wrapper, or labeling of the device or device package.

(h) Any term defined in section 201 of the act shall have that meaning.

(i) Restricted device means a device for which the Commissioner, by regulation under §801.109 of this chapter or otherwise under section 520(e) of the act, has restricted sale, distribution, or use only upon the written or oral authorization of a practitioner licensed by law to administer or use the device or upon such other conditions as the Commissioner may prescribe.

(j) Classification name means the term used by the Food and Drug Administration and its classification panels to describe a device or class of devices for purposes of classifying devices under section 513 of the act.

(k) Representative sampling of advertisements means typical advertising material that gives the promotional claims made for the device.

(l) Representative sampling of any other labeling means typical labeling material (excluding labels and package inserts) that gives the promotional claims made for the device.

(m) Material change includes any change or modification in the labeling or advertisements that affects the identity or safety and effectiveness of the device. These changes may include, but are not limited to, changes in the common or usual or proprietary name, declared ingredients or components, intended use, contraindications, warnings, or instructions for use. Changes that are not material may include graphic layouts, grammar, or correction of typographical errors which do not change the content of the labeling, changes in lot number, and, for devices where the biological activity or known
composition differs with each lot produced, the labeling containing the actual values for each lot.

(p) Class III certification means a certification that the submitter of the 510(k) has conducted a reasonable search of all known information about the class III device and other similar, legally marketed devices.

(q) Class III summary means a summary of the types of safety and effectiveness problems associated with the type of device being compared and a citation to the information upon which the summary is based. The summary must be comprehensive and describe the problems to which the type of device is susceptible and the causes of such problems.

(r) United States agent means a person residing or maintaining a place of business in the United States whom a foreign establishment designates as its agent. This definition excludes mailboxes, answering machines or services, or other places where an individual acting as the foreign establishment’s agent is not physically present.

(s) Wholesale distributor means any person (other than the manufacturer or the initial importer) who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user.

Subpart B—Procedures for Device Establishments

§ 807.20 Who must register and submit a device list?

(a) An owner or operator of an establishment not exempt under section 510(g) of the act or subpart D of this part who is engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for human use shall register and submit listing information for those devices in commercial distribution, except that registration and listing information may be submitted by the parent, subsidiary, or affiliate company for all the domestic or foreign establishments under the control of one of these organizations when operations are conducted at more than one establishment and there exists joint ownership and control among all the establishments. The term “device” includes all in vitro diagnostic products and in vitro diagnostic biological products not subject to licensing under section 351 of the Public Health Service Act. An owner or operator of an establishment located in any State as defined in section 201(a)(1) of the act shall register its name, places of business, and all establishments and list the devices whether or not the output of the establishments or any particular device so listed enters interstate commerce. The registration and listing requirements shall pertain to any person who:

(1) Initiates or develops specifications for a device that is to be manufactured by a second party for commercial distribution by the person initiating specifications;