

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 803, 806, 807, 814, 820, and 1005

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**Medical Device Reports; Reports of Corrections and Removals;
Establishment Registration and Device Listing: Premarket Approval
Supplements; Quality System Regulation; Importation of Electronic
Products; Technical Amendment**

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is correcting certain regulations in 21 CFR parts 803, 806, 807, 814, 820, and 1005. This rule corrects some inadvertent typographical errors and some technical errors, and it is intended to improve the accuracy of the agency's regulations.

EFFECTIVE DATE: *[Insert date of publication in the Federal Register.]*

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SUPPLEMENTARY INFORMATION:

I. Highlights of Final Rule

FDA is making the following changes in several regulations concerning medical devices and radiological health to correct errors, and update addresses and form numbers:

1. FDA is revising 21 CFR 803.18(e) to eliminate a reference to 21 CFR 820.162, a section which no longer exists.

2. FDA is amending §§ 806.10(f), 820.198(d), and 820.200(c) to eliminate references to 21 CFR part 804, a part which no longer exists.

3. FDA is revising the FDA forms numbers listed in certain sections of part 807 (21 CFR part 807), specifically §§ 807.22, 807.25, 807.26, 807.30, 807.35, and 807.37, to identify the forms correctly.

4. FDA is updating the address in § 807.22 (a).

5. FDA is amending § 807.26 to conform to FDA's existing procedure. Changes made between annual registration periods are now done by submitting a letter and need not be submitted on a specific form.

6. FDA is updating the address in §§ 807.37 (a) and (b)(2)

7. FDA is amending § 807.30 by removing references to block numbers for FDA forms. FDA has changed these forms from time to time and, therefore, the numbers are no longer accurate.

8. FDA is amending § 814.39 by moving part of § 814.39(f) to § 814.39(e). This paragraph was inadvertently placed in paragraph (f) after an amendment published on October 8 1998 (63 FR 54043).

9. FDA is amending § 1005.3 by replacing the references to section 358 of the act with section "534 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360kk)." This correction conforms to the redesignation of this section by the Safe Medical Devices Act of 1990.

II. Environmental Impact

The agency has determined under 21 CFR 25.30(i) that this final rule is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement was required. The changes in these amendments do not alter this conclusion.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the final rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule only corrects errors in existing regulations and does not change in any way how devices are regulated, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

IV. Paperwork Reduction Act of 1995

FDA has determined that this final rule contains no additional collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the

relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required

VI. The Technical Amendment

This rule corrects certain minor errors in existing regulations. This administrative action is limited to changing references to form numbers and block numbers on forms, changing an address to submit information to FDA, eliminating references to no longer existent sections and parts, and realigning two paragraphs to correct a typographical error, but it makes no changes in substantive requirements.

This document is published as a final rule with the effective date given previously. Because the final rule is an administrative action, FDA has determined that it has no substantive impact on the public. It imposes no costs, and merely makes technical administrative changes in the Code of Federal Regulations (CFR) for the convenience of the public. FDA, therefore, for good cause, finds under 5 U.S.C. 553(b)(3)(B) and (d)(3) that notice and public comment are unnecessary.

List of Subjects

21 CFR Part 803

Imports, Medical devices, Reporting and recordkeeping requirements

21 CFR Part 806

Imports, Medical devices, Reporting and recordkeeping requirements

21 CFR Part 807

Confidential business information, Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 814

Administrative practice and procedure, Confidential business information, Medical devices, Medical research, Reporting and recordkeeping requirements.

21 CFR Part 820

Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 1005

Administrative practice and procedure, Electronic products, Imports, Radiation protection, Surety bonds.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 803, 806, 807, 814, 820, and 1005 are amended as follows:

PART 803—MEDICAL DEVICE REPORTING

■ 1. The authority section for part 803 continues to read as follows:

Authority: 21 U.S.C. 352, 360, 360i, 360j, 371, 374.

■ 2. Section 803.18(e) is revised to read as follows:

§ 803.18 Files and distributor records.

* * * * *

(e) The manufacturer may maintain MDR event files as part of its complaint file, under § 820.198 of this chapter, provided that such records are prominently identified as MDR reportable events. A report submitted under this subpart A shall not be considered to comply with this part unless the

event has been evaluated in accordance with the requirements of § 820.198 of this chapter. MDR files shall contain an explanation of why any information required by this part was not submitted or could not be obtained. The results of the evaluation of each event are to be documented and maintained in the manufacturer’s MDR event file.

PART 806—MEDICAL DEVICES; REPORTS OF CORRECTIONS AND REMOVALS

- 3. The authority section for part 806 continues to read as follows:

Authority: 21 U.S.C. 352, 360, 360i, 360j, 371, 374.

- 4. Section 806.10(f) is revised to read as follows:

§ 806.10 Reports of corrections and removals.

* * * * *

(f) No report of correction or removal is required under this part, if a report of the correction or removal is required and has been submitted under parts 803 or 1004 of this chapter.

PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND INITIAL IMPORTERS OF DEVICES

- 5. The authority citation for 21 CFR part 807 continues to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 360, 360c, 360e, 360i, 360j, 371, 374.

- 6. Section 807.22 is amended by revising paragraph (b) to read as follows:

§ 807.22 How and where to register establishments and list devices.

* * * * *

(b) The initial listing of devices and subsequent June and December updatings shall be on form FDA–2892 (Medical Device Listing). Forms are obtainable upon request as described in paragraph (a) of this section. A

separate form FDA-2892 shall be submitted for each device or device class listed with the Food and Drug Administration. Devices having variations in physical characteristics such as size, package, shape, color, or composition should be considered to be one device: *Provided*, The variation does not change the function or intended use of the device. In lieu of form FDA-2892, tapes for computer input or hard copy computer output may be submitted if equivalent in all elements of information as specified in form FDA-2892. All formats proposed for use in lieu of form FDA-2892 require initial review and approval by the Food and Drug Administration.

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■ 7. Section 807.25 is amended by revising paragraphs (a) and (f)(1), (f)(2), and (f)(6), and (f)(7) as follows: -

§ 807.25 Information required or requested for establishment registration and device listing.

(a) Form FDA-2891 and Form FDA-2891(a) are the approved forms for initially providing the information required by the act and for providing annual registration, respectively. The required information includes the name and street address of the device establishment, including post office code, all trade names used by the establishment, and the business trading name of the owner or operator of such establishment.

* * * * *

(f) * * *

(1) The identification by classification name and number, proprietary name, and common or usual name of each device being manufactured, prepared, propagated, compounded, or processed for commercial distribution that has not been included in any list of devices previously submitted on form FDA-2892.

(2) The Code of Federal Regulations citation for any applicable standard for the device under section 514 of the act or section 358 of the Public Health Service Act.

* * * * *

(6) Other general information requested on form FDA-2892, i.e.,

(i) if the submission refers to a previously listed device, as in the case of an update, the document number from the initial listing document for the device,

(ii) the reason for submission,

(iii) the date on which the reason for submission occurred,

(iv) the date that the form FDA-2892 was completed,

(v) the owner's or operator's name and identification number.

(7) Labeling or other descriptive information (e.g., specification sheets or catalogs) adequate to describe the intended use of a device when the owner or operator is unable to find an appropriate FDA classification name for the device.

■ 8. Section 807.26 is revised to read as follows:

§ 807.26 Amendments to establishment registration.

Changes in individual ownership, corporate or partnership structure, or location of an operation defined in § 807.3(c) shall be submitted on Form FDA-2891(a) at the time of annual registration, or by letter if the changes occur at other times. This information shall be submitted within 30 days of such changes. Changes in the names of officers and/or directors of the corporation(s) shall be filed with the establishment's official correspondent and shall be provided to the Food and Drug Administration upon receipt of a written request for this information.

■ 9. Section 807.30 is revised to read as follows:

§ 807.30 Updating device listing information.

(a) Form FDA-2892 shall be used to update device listing information. The preprinted original document number of each form FDA-2892 on which the device was initially listed shall appear on the form subsequently used to update the listing information for the device and on any correspondence related to the device.

(b) An owner or operator shall update the device listing information during each June and December or, at its discretion, at the time the change occurs. Conditions that require updating and information to be submitted for each of these updates are as follows:

(1) If an owner or operator introduces into commercial distribution a device identified with a classification name not currently listed by the owner or operator, then the owner or operator must submit form FDA-2892 containing all the information required by § 807.25(f).

(2) If an owner or operator discontinues commercial distribution of all devices in the same device class, i.e., with the same classification name, the owner or operator must submit form FDA-2892 containing the original document number of the form FDA-2892 on which the device class was initially listed, the reason for submission, the date of discontinuance, the owner or operator's name and identification number, the classification name and number, the proprietary name, and the common or usual name of the discontinued device.

(3) If commercial distribution of a discontinued device identified on a form FDA-2892 filed under paragraph (b)(2) of this section is resumed, the owner or operator must submit on form FDA-2892 a notice of resumption containing: the original document number of the form initially used to list that device

class, the reason for submission, date of resumption, and all other information required by § 807.25(f).

(4) If one or more classification names for a previously listed device with multiple classification names has been added or deleted, the owner or operator must supply the original document number from the form FDA-2892 on which the device was initially listed and a supplemental sheet identifying the names of any new or deleted classification names.

(5) Other changes to information on form FDA-2892 will be updated as follows:

(i) Whenever a change occurs only in the owner or operator name or number, e.g., whenever one company's device line is purchased by another owner or operator, it will not be necessary to supply a separate form FDA-2892 for each device. In such cases, the new owner or operator must follow the procedures in § 807.26 and submit a letter informing the Food and Drug Administration of the original document number from form FDA-2892 on which each device was initially listed for those devices affected by the change in ownership.

(ii) The owner or operator must also submit update information whenever establishment registration numbers, establishment names, and/or activities are added to or deleted from form FDA 2892. The owner or operator must supply the original document number from the form FDA-2892 on which the device was initially listed, the reason for submission, and all other information required by § 807.25(f).

(6) Updating is not required if the above information has not changed since the previously submitted list. Also, updating is not required if changes occur

in proprietary names, in common or usual names, or to supplemental lists of unclassified components or accessories.

■ 10. Section 807.35 is revised to read as follows:

§ 807.35 Notification of registrant.

(a) The Commissioner will provide to the official correspondent, at the address listed on the form, a validated copy of Form FDA-2891 or Form FDA-2891(a) (whichever is applicable) as evidence of registration. A permanent registration number will be assigned to each device establishment registered in accordance with these regulations.

(b) Owners and operators of device establishments who also manufacture or process blood or drug products at the same establishment shall also register with the Center for Biologics Evaluation and Research and Center for Drug Evaluation and Research, as appropriate. Blood products shall be listed with the Center for Biologics Evaluation and Research, Food and Drug Administration, pursuant to part 607 of this chapter; drug products shall be listed with the Center for Drug Evaluation and Research, Food and Drug Administration, pursuant to part 207 of this chapter.

(c) Although establishment registration and device listing are required to engage in the device activities described in § 807.20, validation of registration and the assignment of a device listing number in itself does not establish that the holder of the registration is legally qualified to deal in such devices and does not represent a determination by the Food and Drug Administration as to the status of any device.

■ 11. Section 807.37 is revised to read as follows:

§ 807.37 Inspection of establishment registration and device listings.

(a) A copy of the forms FDA-2891 and FDA-2891a filed by the registrant will be available for inspection in accordance with section 510(f) of the act,

at the Center for Devices and Radiological Health (HFZ-308), Food and Drug Administration, Department of Health and Human Services, 9200 Corporate Blvd., Rockville, MD 20850-4015. In addition, there will be available for inspection at each of the Food and Drug Administration district offices the same information for firms within the geographical area of such district office. Upon request, verification of registration number or location of a registered establishment will be provided.

(b)(1) The following information filed under the device listing requirements will be available for public disclosure:

- (i) Each form FDA-2892 submitted;
- (ii) All labels submitted;
- (iii) All labeling submitted;
- (iv) All advertisements submitted;
- (v) All data or information that has already become a matter of public knowledge.

(2) Requests for device listing information identified in paragraph (b)(1) of this section should be directed to the Center for Devices and Radiological Health (HFZ-308), Food and Drug Administration, Department of Health and Human Services, 9200 Corporate Blvd., Rockville, MD 20850-4015.

(3) Requests for device listing information not identified in paragraph (b)(1) of this section shall be submitted and handled in accordance with part 20 of this chapter.

PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES

■ 12. The authority citation for 21 CFR part 814 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 353, 360, 360c-360j, 371, 372, 373, 374, 375, 379, 379e, 381.

■ 13. Section 814.39 is amended by revising paragraphs (e) and (f) to read as follows:

§ 814.39 PMA supplements.

* * * * *

(e)(1) FDA will identify a change to a device for which an applicant has an approved PMA and for which a PMA supplement under paragraph (a) is not required. FDA will identify such a change in an advisory opinion under § 10.85, if the change applies to a generic type of device, or in correspondence to the applicant, if the change applies only to the applicant's device. FDA will require that a change for which a PMA supplement under paragraph (a) is not required be reported to FDA in:

- (i) A periodic report under § 814.84 or
- (ii) A 30-day PMA supplement under this paragraph.

(2) FDA will identify, in the advisory opinion or correspondence, the type of information that is to be included in the report or 30-day PMA supplement. If the change is required to be reported to FDA in a periodic report, the change may be made before it is reported to FDA. If the change is required to be reported in a 30-day PMA supplement, the change may be made 30 days after FDA files the 30-day PMA supplement unless FDA requires the PMA holder to provide additional information, informs the PMA holder that the supplement is not approvable, or disapproves the supplement. The 30-day PMA supplement shall follow the instructions in the correspondence or advisory opinion. Any 30-day PMA supplement that does not meet the requirements of the correspondence or advisory opinion will not be filed and, therefore, will not be deemed approved 30 days after receipt.

(f) Under section 515(d) of the act, modifications to manufacturing procedures or methods of manufacture that affect the safety and effectiveness of a device subject to an approved PMA do not require submission of a PMA supplement under paragraph (a) of this section and are eligible to be the subject of a 30-day notice. A 30-day notice shall describe in detail the change, summarize the data or information supporting the change, and state that the change has been made in accordance with the requirements of part 820 of this chapter. The manufacturer may distribute the device 30 days after the date on which FDA receives the 30-day notice, unless FDA notifies the applicant within 30 days from receipt of the notice that the notice is not adequate. If the notice is not adequate, FDA shall inform the applicant in writing that a 135-day PMA supplement is needed and shall describe what further information or action is required for acceptance of such change. The number of days under review as a 30-day notice shall be deducted from the 135-day PMA supplement review period if the notice meets appropriate content requirements for a PMA supplement.

PART 820—QUALITY SYSTEM REGULATION

■ 14. The authority citation for 21 CFR part 820 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383.

■ 15. Section 820.198(d) is revised to read as follows

§ 820.198 Complaint files.

* * * * *

(d) Any complaint that represents an event which must be reported to FDA under part 803 of this chapter shall be promptly reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate

portion of the complaint files or otherwise clearly identified. In addition to the information required by § 820.198(e), records of investigation under this paragraph shall include a determination of:

- (1) Whether the device failed to meet specifications;
- (2) Whether the device was being used for treatment or diagnosis; and
- (3) The relationship, if any, of the device to the reported incident or adverse event

* * * * *

■ 16. Section 820.200(c) is revised to read as follows:

§ 820.200 Servicing.

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(c) Each manufacturer who receives a service report that represents an event which must be reported to FDA under part 803 of this chapter shall automatically consider the report a complaint and shall process it in accordance with the requirements of § 820.198.

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PART 1005—IMPORTATION OF ELECTRONIC PRODUCTS

■ 17. The authority citation for 21 CFR part 1005 continues to read as follows:

Authority: 42 U.S.C. 263d, 263h.

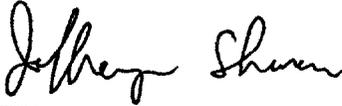
■ 18. Section 1005.3 is revised to read as follows:

§ 1005.3 Importation of noncomplying goods prohibited.

The importation of any electronic product for which standards have been prescribed under section 534 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360kk) shall be refused admission into the United States unless there is affixed to such product a certification in the form of a label or tag in conformity with section 534(h) of the act (21 U.S.C. 360kk(h)). Merchandise

refused admission shall be destroyed or exported under regulations prescribed by the Secretary of the Treasury unless a timely and adequate petition for permission to bring the product into compliance is filed and granted under §§ 1005.21 and 1005.22.

Dated: 3/02/04
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Jeffrey Shuren,
Assistant Commissioner for Policy.

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