

DMB

Display Date	9.28.98
Publication Date	9.29.98
Certifier	J. [Signature]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 807

[Docket No. 98 N-0520]

Medical Devices; Establishment Registration and Device Listing for Manufacturers and Distributors of Devices; Companion to Direct Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend certain regulations governing establishment registration and device listing by domestic distributors. This proposed rule is a companion document to the direct final rule published elsewhere in this issue of the Federal Register. These amendments are being made to implement revisions to the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA). This companion proposed rule is being issued under FDAMA and the act as amended.

DATES: Comments must be received on or before (*insert date 75 days after date of publication in the Federal Register*).

ADDRESSES: Submit written comments on the companion proposed rule to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Walter W. Morgenstem, Center for Devices and Radiological Health (HFZ-305), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20852.

SUPPLEMENTARY INFORMATION:

I. Background

This proposed rule is a companion to the direct final rule published in the final rules section of this issue of the Federal Register. The direct final rule and this companion proposed rule are substantively identical. FDA is publishing the direct final rule because the rule contains noncontroversial changes, and FDA anticipates that it will receive no significant adverse comment. A detailed discussion of this rule is set forth in the preamble of the direct final rule. If no significant adverse comment is received in response to the direct final rule, no further action will be taken related to this proposed rule. Instead, FDA will publish a confirmation document within 30 days after the comment period ends confirming that the direct final rule will go into effect on (insert *date 135 days after date of publication in the* Federal Register). Additional information about FDA's direct final rulemaking procedures is set forth in a guidance published in the Federal Register of November 21, 1997 (62 FR 62466).

If FDA receives any significant adverse comment regarding ^{the direct final} ~~this proposed rule~~, FDA will publish a document withdrawing the direct final rule within **30** days after the comment period ends and will proceed to respond to **all** of the comments under this companion proposed rule using usual notice-and-comment procedures. The comment period for this companion proposed rule runs concurrently with the direct final rule's comment period. Any comments received under this companion proposed rule will also be considered as comments regarding the direct final rule. JF
per
Vine
and
Mark...

A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether a significant adverse comment is sufficient to terminate a direct final **rulemaking**, FDA will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process. Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered adverse under this procedure. For example, a comment recommending a rule change in addition

to the rule will not be considered a significant adverse comment, unless the comment states why the rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to part of a rule and that part can be severed from the remainder of the rule, FDA may adopt as final those parts of the rule that are not the subject of a significant adverse comment.

This action is part of FDA's continuing effort to achieve the objectives of the President's "Reinventing Government" initiative, and is intended to reduce the burden of unnecessary regulations on medical devices without diminishing the protection of public health.

On November 21, 1997, the President signed FDAMA into law (Pub. L. 105-115). Section 213(b) of FDAMA made the following changes to section 510(g) of the act (21 U.S.C. 360(g)) regarding establishment registration and device listing by domestic distributors:

1. FDAMA amended section 510(g) of the act to add a new paragraph (g)(4) to provide that the registration and listing requirements of section 510 of the act do not apply to distributors who act as "wholesale distributors," and who do not manufacture, repackage, process, or relabel a device,

2. FDAMA also added a definition of "wholesale distributor" to section 510(g) of the act. A "wholesale distributor" is defined as "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."

FDA is issuing this companion proposed rule to amend certain existing regulations to conform to amendments made by FDAMA to section 510(g) of the act. For a discussion of the specific provisions of the regulation, see the preamble to the direct final rule published elsewhere in this issue of the Federal Register.

II. Environmental Impact

The agency has determined under 21 **CFR** 25.30(h) that this proposed action 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 is required,

III. Analysis of Impacts

FDA has examined the impact of this companion proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601-612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Pub. L. 104-121)), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulatory action 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 proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, this proposed 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. The rule codifies applicable statutory requirements imposed by FDAMA. Because the companion proposed rule exempts certain distributors from registration and device listing, it may permit more small competitors to enter the marketplace. The agency certifies that this proposed rule, if issued, will not have a significant economic impact on a substantial number of small entities. In addition, this proposed rule does not impose a mandate that results in an expenditure of \$100 million or more in either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

IV. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required.

V. Submission of Comments

Interested persons may, on or before (*insert date 75 days after date of publication in the Federal Register*), submit to the Dockets Management Branch (address above) written comments regarding this proposal. The comment period runs concurrently with the comment period for the direct final rule. Two copies of any comment are to be submitted except that individuals may submit one copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. All comments received will be considered as comments regarding the direct final rule and this proposed rule. In the event the direct final rule is withdrawn, all comments received will be considered comments on the proposed rule.

List of Subjects in 21 CFR Part 807

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

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 807 be amended as follows:

1. The part heading for part 807 is revised to read as follows:

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

2. 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,

3. Section 807.3 is amended by revising paragraphs (d)(2) and (g), and by adding paragraph (s) to read as follows:

§ 807.3 Definitions.

* * * * *

(d) * * *

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

* * * * *

(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.

* * * * *

(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.

4. Section 807.20 is amended by revising paragraph (a)(4), by redesignating paragraph (d) as paragraph (c) and paragraph (c) as paragraph (d), respectively, and by adding paragraph (c)(3) to read as follows:

§ 807.20 Who must register and submit a device list.

(a) * * *

(4) Acts as an initial importer;

* * * * *

(c) * * *

(3) Acts as a wholesale distributor, as defined in § 807,3(s), and who does not manufacture, repackage, process, or relabel a device.

* * * * *



§ 807.22 [Amended]

5. Section 807.22 *How and where to register establishments and list devices* is amended in paragraph (c) by removing the words “distributor” and “distributors” each time they appear and by adding in their place the words “initial importer” and “initial importers”, respectively.

Dated: July 15, 1998
July 15, 1998

William B. Schultz

William B. Schultz J
Deputy Commissioner for Policy

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

Jan Windsor

[FR Dec. 98-'???? Filed ??-??-98; 8:45 am]

BILLING CODE 4160-01-F