some products containing clotrimazole were approved for OTC marketing under an NDA. These manufacturers can make this change whenever they are ready to order new product labeling. Manufacturers have informed the agency that this type of relabeling cost generally averages about $2,000 to $3,000 per stock keeping unit (SKU) (individual products, packages, and sizes). Based on information in the agency's Drug Listing System, there are less than 10 manufacturers and distributors that together produce about 25 SKUs of OTC topical antifungal drug products that contain clotrimazole. Assuming that there are about 25 affected OTC SKUs in the marketplace, total one-time costs of relabeling would be $50,000 to $75,000. Because the manufacturers can make the changes when they are ready to reorder product labeling stock, the incremental costs of the added warning will, for the most part, be mitigated. In making this change, these manufacturers would save money by eliminating all costs associated with maintaining an NDA. Likewise, other manufacturers who now wish to market topical clotrimazole drug products will be able to enter the marketplace without the costs associated with an NDA. Their costs would involve the standard startup costs of any OTC drug marketed under the monograph.

Because no small firms will be adversely affected, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

IV. Paperwork Reduction Act of 1995

FDA concludes that the labeling requirements for clotrimazole are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Rather, the existing monograph labeling is a ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

V. Environmental Impact

The agency has determined under 21 CFR 25.31(a) that this 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.

VI. 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.

List of Subjects in 21 CFR Part 333

Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 333 is amended as follows:

PART 333—TOPICAL ANTIMICROBIAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR part 333 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

2. Section 333.210 is amended by adding paragraph (g) to read as follows:

§ 333.210 Antifungal active ingredients.

* * * * *

(g) Clotrimazole 1 percent.

Dated: January 30, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–3079 Filed 2–7–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 821

[Docket No. 00N–1034]

Medical Devices; Device Tracking

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the medical device tracking regulation. FDA is making substantive changes to revise the scope of the regulation and add certain patient confidentiality requirements, and nonsubstantive changes to remove outdated references and simplify terminology. These revisions are made to conform the regulation to changes made in section 519(e) of the Federal Food, Drug, and Cosmetic Act (the act) by the FDA Modernization Act of 1997 (FDAMA), and to simplify certain requirements.

DATES: This rule is effective May 9, 2002. The information collection provisions of this final rule have been submitted to the Office of Management and Budget (OMB) for review. Prior to the effective date of this final rule, FDA will publish in the **Federal Register** a notice announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule.

FOR FURTHER INFORMATION CONTACT: Chester T. Reynolds, Center for Devices and Radiological Health (HFZ–300), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4618.

SUPPLEMENTARY INFORMATION:

I. Current Statutory Tracking Provisions (As Amended by FDAMA)

Section 211 of FDAMA (Public Law 105–115) became effective on February 19, 1998. It amended the previous tracking provisions in section 519(e)(1) and (e)(2) of the act (21 U.S.C. 360i(e)(1) and (e)(2)) that were added by the Safe Medical Devices Act (SMDA). Unlike the tracking provisions under SMDA, which required tracking for any device meeting certain criteria, FDAMA allows FDA discretion in applying tracking requirements to devices that meet certain criteria and provides that tracking requirements can be imposed only after FDA issues an order.

Current section 519(e)(1) of the act, as amended by FDAMA, provides that FDA may by order require a manufacturer to adopt a method of tracking a class II or class III device if: (1) Its failure would be reasonably likely to have serious adverse health consequences, or (2) it is intended to be implanted in the human body for more than 1 year, or (3) it is a life-sustaining or life-supporting device used outside a device user facility. FDA interprets the discretion inherent in the language ''may by order require'' tracking to allow the agency to consider additional relevant factors in determining whether to issue a tracking order for a device that meets the statutory threshold tracking criteria set out in current section 519(e)(1) of the act.

As amended by FDAMA, current section 519(e)(2) of the act provides that patients receiving a device subject to

tracking may refuse to release, or refuse permission to release, their names, addresses, social security numbers, or other identifying information for tracking purposes.

The discretionary authority to issue tracking orders, and the three statutory criteria that operate independently of one another in section 519(e)(1) of the act, allow FDA to accomplish the intended purpose of device tracking under FDAMA, as identified by Congress, i.e., to facilitate the recall of dangerous or defective devices, under section 518(e) of the act (21 U.S.C. 360h(e)) (S. Rept. 108, 105th Cong., 1st sess. 37 (1997)).

II. Steps Taken to Implement FDAMA Tracking Authority and Conform the Tracking Regulation to Current Tracking Provisions Under FDAMA

A. Implementing Statutory Tracking Authority Under FDAMA

1. Public Meeting/Manufacturer Notification

In the **Federal Register** of December 18, 1997 (62 FR 66373), FDA announced its intent to conduct a public meeting in Rockville, MD, to discuss changes in medical device tracking. This meeting occurred on January 15,1998.

On December 19, 1997, FDA sent letters to manufacturers with device tracking responsibilities under section 519(e) of the act. The letters explained that FDA would implement statutory changes in medical device tracking under FDAMA. The letters advised that existing tracking requirements imposed by previously issued FDA regulations or FDA orders would remain in effect until FDA notified a firm of any changes in its responsibilities.

At the January 15, 1998, public meeting, comments from consumer groups, clinicians, manufacturers, and industry associations suggested nonbinding factors that FDA should consider, in addition to the tracking criteria set out under FDAMA, to determine whether tracking should be ordered by FDA.

2. Issuance of Tracking Orders Under FDAMA

On February 11, 1998, FDA issued orders to manufacturers of 28 types of devices, which the agency determined met the revised tracking criteria in section 519(e) of the act, as amended by FDAMA. These ''new'' orders became effective on February 19, 1998, the effective date of the revised tracking provision under FDAMA. The devices ordered to be tracked included 26 device types previously identified as subject to tracking under the SMDA criteria in the tracking regulation at § 821.20(b)(1), (b)(2), and (c) (21 CFR 821.20(b)(1), (b)(2), and (c)). Arterial stents and intraocular lenses, which had not been listed previously as subject to tracking in the regulation, also were ordered to be tracked under FDAMA.

3. Rescission of Certain Tracking Orders Issued Under FDAMA

Beginning on August 26, 1998, FDA rescinded the tracking orders issued on February 19, 1998, for 14 types of devices, including intraocular lenses and arterial stents.

FDA determined, in light of its discretionary authority under FDAMA, that these 14 device types did not warrant continued tracking based on additional factors, even though the statutory criteria were met. The additional and nonbinding factors FDA considered included: (1) The likelihood of sudden, catastrophic failure; (2) the likelihood of significant adverse clinical outcomes; and (3) the need for prompt professional intervention.

4. Issuance of Additional FDAMA Tracking Orders

On December 14, 1998, FDA issued orders to manufacturers of dura mater devices, requiring them to track the devices under section 519(e) of the act, as amended by FDAMA. These medical devices met the statutory criteria and may have significant adverse clinical outcomes.

On September 28, 1999, FDA issued orders to manufacturers of stent grafts intended to treat abdominal aortic aneurysms (AAA), requiring them to track the devices.

Upon reviewing premarket applications, the agency determined these devices met the statutory tracking criteria of amended section 519(e) of the act, because their failure would be reasonably likely to have serious adverse consequences, and also would necessitate prompt professional intervention.

In April, August, and October 2000, FDA issued tracking orders to seven firms that received agency clearance to market devices of the type the agency had already subjected to the tracking requirement. Three of these firms had not tracked devices before. They received FDA orders to track the replacement heart valves, temporomandibular joint (TMJ) prostheses, and continuous ventilators they marketed, as other firms had been ordered to do before them. The four other firms were already tracking other models of the cardiovascular permanently implantable pacemaker electrodes and continuous ventilators that they were ordered to track in 2000.

5. Availability of Informative Notices and Explanatory Guidance Documents

FDA published a series of **Federal Register** notices that updated tracking information or announced the availability of further guidance documents. These notices and guidance documents were made available to the public at the agency Web site, http://www.fda.gov/cdrh/fedregin.html. They were as follows:

a. 63 FR 10638, March 4,1998—FDA issued a notice announcing its issuance on February 11, 1998, of new tracking orders under its new authority under FDAMA. These new orders became effective on February 19, 1998, and made 28 types of devices manufactured by specific firms subject to the tracking requirements of section 519(e) of the act, as amended under FDAMA. FDA also announced its intention to exercise its new discretionary authority under FDAMA. The agency advised that it would identify additional nonbinding factors to determine whether tracking requirements, and the issuance of agency tracking orders, were warranted for devices that otherwise qualify to be tracked under section 519(e)(1) of the act criteria.

This notice announced FDA's intention to review and reconsider the imposition of tracking requirements for 13 devices that were identified as meeting the threshold statutory criteria and that were subject to February 1998 tracking orders. FDA solicited public comment on which nonbinding factors it should consider in making such discretionary tracking determinations.

b. 63 FR 10640, March 4, 1998—FDA issued a notice announcing the availability of the guidance document entitled ''Guidance on Medical Device Tracking.'' This document provided guidance to manufacturers and distributors about their tracking responsibilities under section 519(e) of the act, as amended by FDAMA. It discussed which statutory and regulatory requirements had changed, and which requirements remained the same. The guidance represented FDA's thinking at that time on medical device tracking under the FDAMA amendments.

c. 64 FR 7197, February 12, 1999—FDA issued a notice announcing the availability of the revised final guidance document entitled ''Guidance on Medical Device Tracking.'' It replaced the previous guidance issued on March 4, 1998.

The revised February 1999 guidance noted FDA's December 1998 issuance of

tracking orders for dura mater devices and provided an updated list of devices that were subject to tracking orders. It also identified the additional nonbinding factors that FDA may use, in addition to the statutory criteria, to decide whether to require the tracking of a device. The factors mentioned included: The likelihood of sudden, catastrophic failure or significant, adverse clinical outcomes, and the need for prompt professional intervention.

d. 64 FR 3722, January 24, 2000—FDA issued a notice announcing the availability of an updated and revised ''Guidance on Medical Device Tracking'' that both reaffirmed previous agency positions regarding FDAMA revised tracking requirements and clarified current thinking regarding certain devices subject to tracking requirements.

The January 24, 2000, revised guidance document clarified that the category of replacement heart valves that must be tracked is limited to mechanical heart valves only and does not include human allograft (tissue) heart valves. The January 2000 guidance stated that FDA reevaluated the tracking status of infusion pumps because their labeling does not always make clear the types of fluids the pumps are intended to deliver.

Infusion pump labeling statements became an issue when the previous February 1999 guidance document identified infusion pumps as devices subject to tracking, ''except those designated and labeled for use exclusively for fluids with low potential risks, such as enteral feeding or anti-infectives.'' FDA experience, upon reexamination, was that most infusion pumps have labeling that is general in nature, i.e, they are intended ''to deliver medications,'' and very few pumps are labeled with a specific indication. Thus, there was uncertainty whether product labels would provide sufficient information to determine which infusion pumps must be tracked.

To reduce the above uncertainties and clarify FDA's position, the January 2000 guidance stated that tracking is required only for electromechanical infusion pumps used outside device user facilities. Thus, FDA's current position is that tracking is not needed for elastomeric, electromechanical, gravity flow, and other infusion pumps used in hospitals and other device user facilities. This also means that FDA does not consider tracking warranted for elastomeric and gravity flow pumps used outside device user facilities, based on the regulatory history of these products. A firm may request a tracking variance or exemption under § 821.2 (21 CFR 821.2) for an electromechanical infusion pump used outside a device user facility if the firm can demonstrate that the pump is labeled and used solely to administer fluids with low potential risks.

B. Proposed Rule Amending Current Tracking Regulation

In the **Federal Register** of April 25, 2000 (65 FR 24144), FDA published a proposal to amend the existing medical device tracking regulation part 821 (21 CFR part 821) to conform to statutory changes made by FDAMA in the scope, authority, criteria, and confidentiality requirements of tracking. FDA proposed:

- Revising the existing scope and authority set out in §§ 821.1 and 821.20;
- Modifying existing definitions of ''importer'' (§ 821.3(b)) and ''permanently implantable device'' (§ 821.3(f));
- Removing existing criteria, responsibilities, and authority from § 821.20(b)(1), (b)(2), and (c); and
- Adding new patient confidentiality provisions in new § 821.55(a), and references to new § 821.55(a) to existing § 821.30(b)(3) and (c)(1)(iii).

For simplification, FDA further proposed nonsubstantive changes to remove unneeded references to the 1993 effective date of tracking provisions in § 821.1(c), and to outdated procedures for citizen petitions received before August 29, 1993, in § 821.2(d). FDA also proposed substituting the simple inclusive term ''tracked devices'' to replace the more complex detail describing devices subject to tracking in existing § 821.25(a)(2) and (a)(3).

FDA did not propose changes in parts of the existing regulation that were not affected by FDAMA. Except for the nonsubstantive changes described above, FDA did not propose changes in the regulation with respect to: Existing system and content requirements for tracking; existing obligations of persons other than device manufacturers, such as distributors; existing records and inspection requirements; and existing record retention requirements.

III. Public Comment on Proposal to Amend Tracking Regulation

FDA received just one comment on its April 25, 2000 (65 FR 24144 at 24145), proposal. The comment came from a device firm. It identified a reference in the preamble of the proposal to clarifications made by FDA concerning infusion pumps subject to tracking. FDA had discussed which infusion pumps are covered by the tracking orders it issued, under FDAMA, in nonbinding guidance documents that the agency made available to the public on February 12, 1999 (64 FR 7197), and an updated and revised version that FDA made available on January 24, 2000 (65 FR 3722).

The comment maintained that infusion pumps should be tracked on the basis of high-risk uses (per FDA's February 1999 guidance) rather than on operating technology, i.e., whether or not they are electromechanical infusion pumps (per FDA's January 2000 guidance). The comment claimed that FDA's position in the January 2000 guidance ''* * * would, again, make enteral feeding pumps which are electromechanical in nature, subject to tracking, while unfairly exempting enteral feeding pumps which are not electromechanical.''

The issue raised by the comment is outside the scope of the regulation. Specifically, the comment relates to the appropriateness of the issuance of orders that were issued under section 519(e) of the act as amended by FDAMA, prior to the existence of this proposed regulation. The comment also relates to the appropriateness of guidance that was published prior to the existence of this proposed regulation. Since the issuance of these orders relating to infusion pumps took place under authority that was independent of the proposed regulation, the appropriateness of the order's issuance is not within the scope of this regulation.

FDA does note, however, that in describing the criteria for triggering the issuance of the future orders that will be issued under the regulation, the regulation mirrors the language of the statute. If it has concerns about the issuance of previous orders relating to infusion pumps, the firm may request an exemption from the tracking regulations, and may also submit comments on the guidance relating to the application of tracking requirements to infusion pumps.

IV. Corrective Changes to Tracking Regulation

A. Summary of Changes

On February 19, 1998, FDAMA amended section 519(e) of the act. By operation of statute, certain provisions in the current tracking regulation, part 821, became inconsistent with the tracking requirements as revised by FDAMA. On April 25, 2000, FDA published in the **Federal Register** (65 FR 24144) a proposal to amend the existing medical device tracking regulation (part 821) to conform to statutory changes made by FDAMA in

the scope, authority, criteria, and confidentiality requirements of tracking.

This final rule incorporates, unchanged, all of the proposed revisions that the agency set out in its April 25, 2000, proposal to amend the existing regulation. In particular, the final rule revises certain sections of part 821 to conform to section 519 of the act, as amended. Thus, FDA is revising the scope of the tracking requirements, including the appropriate modification of certain definitions and certain requirements relating to patient confidentiality, to reflect FDAMA's changes.

Other than the final changes described above, parts of the tracking regulation that were not affected by FDAMA remain unchanged. Except for the nonsubstantive terminology change noted above, this final rule makes no revisions to:

- The regulation's existing system and content tracking requirements,
- The current obligations of persons other than device manufacturers, such as distributors,
- Records and inspection requirements, and
- Existing record retention requirements.

Each of the revisions made by this final rule amending the existing medical devices tracking regulation is discussed in more detail below.

B. Scope (§ 821.1)

Conformance With FDAMA Tracking Criteria

1. FDA is amending § 821.1 by revising paragraph (a) to conform its language to the statutory language in section 519(e) of the act, as amended by FDAMA.

Under FDAMA, the types of persons subject to tracking are no longer linked to registration requirements under section 510 of the act (21 U.S.C. 360). As amended, the tracking requirements apply only to manufacturers who receive a tracking order from FDA.

FDAMA modifies the criteria for tracking devices. In revised section 519(e)(1) of the act amended by FDAMA, FDA may order a manufacturer to track only a ''class II or class III device—(A) the failure of which would be reasonably likely to have serious adverse health consequences; or (B) which is—(i) intended to be implanted in the human body for more than one year, or (ii) a life sustaining or life supporting device used outside a device user facility.''

FDAMA allows FDA to exercise discretion in determining whether a device that meets the criteria in section 519(e) of the act shall be tracked. This means that, even if the statutory criteria are met, tracking is not required unless FDA issues an order that directs a manufacturer to track a device. Under FDAMA, the statutory criteria establish a minimum threshold. If the device does not meet any of the criteria in section 519(e) of the act, FDA may no longer designate a device as one that requires tracking to protect the public health.

Accordingly, to conform the language in § 821.1(a) to the statutory language in current section 519(e) of the act, FDA is amending section 519(a) to read as follows:

> ''The regulations in this part implement section 519(e) of the Federal Food, Drug, and Cosmetic Act, which provides that the Food and Drug Administration may require a manufacturer to adopt a method of tracking a class II or class III device, if the device meets one of the following three criteria and FDA issues an order to the manufacturer: the failure of the device would be reasonably likely to have serious adverse health consequences; or the device is intended to be implanted in the human body for more than 1 year; or the device is a life-sustaining or life-supporting device used outside a device user facility. A device that meets one of these criteria and is the subject of an FDA order must comply with this part and is referred to, in this part, as a 'tracked device.' ''

Eliminating the Linkage of Tracking to the Registration of a Person as the Manufacturer of a Device

2. FDA is revising the third sentence in paragraph (b) in § 821.1, which describes persons subject to tracking requirements, by removing the words ''must register under section 510 of the act,'' and substituting the words ''are subject to tracking orders.'' As noted above, this change reflects the revisions made to section 519(e) of the act by FDAMA. The revised tracking requirements, as amended by FDAMA, are triggered for the manufacturer by the issuance of an FDA tracking order, not by registration requirements. For clarity, FDA is also revising the second sentence in paragraph (b) in § 821.1 by removing the words ''any person for whom the device is intended'' and substituting the words ''the patient.''

Removing Outdated Requirement

3. FDA is amending § 821.1 by removing paragraph (c). Section 821.1(c) was included in the final tracking regulations issued in 1993 to clarify that the effective date for the tracking requirements under SMDA was August 29, 1993. Because the requirements of these regulations have been in effect since August 29, 1993, and have been implemented by industry for more than 5 years, it is not necessary to include the effective date in the current regulation.

Redesignation of Paragraphs in § 821.1 (Without Revision)

4. In conjunction with the removal of paragraph (c) from § 821.1, FDA is redesignating current paragraphs (d) and (e) in this section as paragraphs (c) and (d), respectively. No changes are made in these redesignated paragraphs.

C. Exemptions and Variances (§ 821.2)

5. FDA is amending § 821.2 by removing paragraph (d). Paragraph (d) refers to the procedures that FDA used to handle tracking petitions received prior to the August 29, 1993, effective date of the tracking regulation. Because FDA has responded to all of those petitions, there is no longer any need to include deadlines and timeframes for these particular petitions.

D. Definitions (§ 821.3)

6. FDA is revising the definition of ''Importer'' in existing § 821.3(b). ''Importer'' was previously defined as ''the initial distributor of an imported device who is required to register under section 510 of the act and § 807.20 of this chapter. ''Importer'' does not include anyone who only performs a service for the person who furthers the marketing, i.e., brokers, jobbers, or warehouser.''

FDA is removing the existing language ''required to register under section 510 of the act and § 807.20 of this chapter,'' from the end of the first sentence in the definition and replacing it with the phrase ''subject to a tracking order.'' For tracking purposes, this change makes the term ''Importer'' mean ''the initial distributor of an imported device who is subject to a tracking order.'' For clarity, FDA is also revising the phrase ''who only performs a service for the person who furthers the marketing,'' to ''who only furthers the marketing.''

Accordingly, this final rule amends § 821.3(b) to read as follows:

''(b) Importer means the initial distributor of an imported device that is subject to a tracking order. ''Importer'' does not include anyone who only furthers the marketing, e.g., brokers, jobbers, or warehousers.''

7. FDA is amending § 821.3(f) by revising the definition of ''Permanently implantable device.'' Previously, § 821.3(f) defined ''Permanently implantable device'' as meaning ''a device that is intended to be placed into a surgically or naturally formed cavity of the human body to continuously assist, restore, or replace the function of an organ system or structure of the human body throughout the useful life of the device. The term does not include

any device which is intended and used for temporary purposes or which is intended for explantation.''

FDAMA amended section 519(e)(1)(B)(i) of the act to provide that FDA only may order tracking of an implanted device if the device ''is intended to be implanted in the human body for more than 1 year.'' Thus, FDA is changing the type of implanted device defined under § 821.3(f) from ''permanently implantable device'' to ''device intended to be implanted in the human body for more than 1 year.''

FDA is also adding the phrase ''for more than 1 year'' in the first sentence of the revised definition after the phrase ''of the human body.'' And, at the end of the second sentence, FDA is adding the phrase ''in 1 year or less.'' These latter two revisions further incorporate into the revised definition the minimum implantation time period established by the FDAMA amendment.

FDA believes that devices implanted for more than 1 year must continue to perform the function for which they were designed and implanted, throughout their useful life. FDA continues to believe that implanted devices which may remain ''permanently'' in the body, but whose function may be replaced by natural or other processes after a given period of time, should not be tracked (57 FR 22973, May 29, 1992). Thus, in revised § 821.3(f), FDA is retaining the ''continuously assist, restore, or replace'' portion of the current definition as a condition of meeting the criterion in section 519(e)(1)(B)(i) of the act.

Accordingly, FDA is amending § 821.3(f) to read as follows:

''(f) Device intended to be implanted in the human body for more than 1 year means a device that is intended to be placed into a surgically or naturally formed cavity of the human body for more than 1 year to continuously assist, restore, or replace the function of an organ system or structure of the human body throughout the useful life of the device. The term does not include any device that is intended and used only for temporary purposes or that is intended for explantation in 1 year or less.''

E. Devices Subject to Tracking (§ 821.20)

Revisions, Removals, and Redesignation

8. FDA is amending § 821.20 by revising paragraph (a), by removing paragraphs (b) and (c), by redesignating paragraph (d) as paragraph (b), and by revising newly redesignated paragraph (b).

Revision for Conformance

9. FDA is revising paragraph (a) to conform § 821.20(a) to the tracking provision of section 519(e) of the act, as amended by FDAMA. The existing paragraph (a) conformed to the tracking provision that was added to the act under section 519(e) by SMDA. That earlier version of section 519(e) of the act required the tracking of devices that met the statutory tracking criteria for devices in section 519(e) and manufacturers made the initial determination whether their devices met the statutory criteria for tracking. It also required the tracking of devices that FDA, in its discretion, designated as requiring tracking.

FDA is revising paragraph (a) of § 821.20 to conform its language to the statutory language of the revised section 519(e) of the act under FDAMA. Accordingly, amended § 821.20(a) requires the manufacturer of a class II or class III device to track the device when ordered by FDA to do so, under the agency's discretion, after making a determination that the device is:

- One the failure of which would be reasonably likely to have serious adverse health consequences, or
- One which is intended to be implanted in the human body for more than a year, or
- One which is life-sustaining or life-supporting and used outside a device user facility, and is
- One which warrants tracking.

Removal of Illustrative Device Lists

10. In the amended regulation, FDA is revising § 821.20, further, by removing paragraphs (b) and (c).

As explained above, the current tracking requirement under section 519(e) of the act, as amended by FDAMA, is triggered solely by the issuance of FDA tracking orders. FDAMA authorizes FDA to exercise its discretion in determining whether a class II or class III device, meeting the criteria for ''trackable'' devices, warrants tracking. FDA must then issue a tracking order to the manufacturer of the class II or class III device when the agency determines that the device warrants being subject to the tracking requirement.

Introductory paragraph (b) and paragraph (b)(1) are being removed because it is no longer necessary to give manufacturers guidance about how to decide whether they should initiate tracking. Under the revisions to section 519(e) of the act by FDAMA, manufacturers no longer need to determine whether their devices are subject to tracking. Instead, FDA makes the determination by order.

Designated Device Lists

11. In the amended regulation, FDA has removed paragraph (c) of § 821.20. That paragraph, which identified devices FDA designated for tracking that did not meet the mandatory tracking criteria under SMDA, is no longer relevant. As amended by FDAMA, section 519(e)(2) of the act no longer allows FDA to designate for tracking devices that do not meet the tracking criteria in section 519(e)(1).

Identifying Tracked Devices to Persons Other Than Manufacturers

12. Although distributors, final distributors, and multiple distributors of tracked devices will not be provided tracking orders, as manufacturers are, FDA believes it can keep such interested parties apprised of revisions to device types subject to tracking orders through the use of guidance or periodic **Federal Register** notices. FDA will make tracking guidance or notices available to interested parties through the agency's Internet and Facts-on-Demand Web sites. FDA will also announce their availability through the publication of **Federal Register** notices.

FDA has already disseminated the status and identification of tracked devices successfully through **Federal Register** notices published on March 4, 1998 (63 FR 10638 and 63 FR 10640); February 12, 1999 (64 FR 7197); and January 24, 2000 (65 FR 3722); and through guidance documents made available through the Internet on these same dates.

Revising and Redesignating Existing § 821.20(b) and (d).

13. In removing previous § 821.20(b) and (c) from the regulation, FDA is redesignating existing paragraph (d) as paragraph (b), and is editing, revising, and deleting provisions of redesignated paragraph (b).

In redesignated § 821.20(b), FDA is revising the language in existing § 821.20(d) describing the content of 510(k) and premarket approval application orders to reflect the fact that tracking requirements are accomplished by order under FDAMA. Revised § 821.20(b) reads as follows: ''When responding to premarket notification submissions and premarket approval applications, FDA will notify the sponsor by issuing an order that states that FDA believes the device meets the criteria of section 519(e)(1) of the act and, by virtue of the order, the sponsor must track the device.''

F. Device Tracking System and Content Requirements: Manufacturer Requirements (§ 821.25)

Revising Terms Used to Describe Tracked Devices

14. FDA is amending § 821.25 by revising the terms currently used in the introductory texts of paragraphs (a)(2) and (a)(3). The term ''tracked device(s)'' replaces existing device descriptions to shorten the identification of the types of devices subject to data requirements set out under § 821.25(a)(2)(i) through (a)(2)(vii) and (a)(3)(i) through (a)(3)(viii). In describing the types of tracked devices that were subject to the reporting requirements in § 821.25(a)(2)(i) through (a)(2)(vii) and (a)(3)(i) through (a)(3)(viii), the existing regulation restated the statutory criteria of section 519(e) of the act, as added by the SMDA, that were used to subject devices to tracking.

FDA is amending the introductory text of § 821.25(a)(2) and (a)(3) to remove descriptions that reflect SMDA criteria that no longer apply.

Revised Terminology

15. FDA is substituting, in revised § 821.25(a)(2) and (a)(3), a description of devices that are subject to reporting requirements that is consistent with the section 519(e) of the act criteria as amended by FDAMA. To simplify, however, FDA is choosing to use the term ''tracked device'' to discuss devices subject to tracking orders under FDAMA, rather than to fully restate the revised FDAMA section 519(e) of the act criteria for tracked devices.

FDA revisions of the introductory texts of final § 821.25(a)(2) and (a)(3) do not change the data reporting requirements for single patient use, implants, or multiple patient use devices that are subject to tracking requirements by virtue of the issuance of a FDA tracking order.

Refusal of Patients to Provide Information

16. FDA further amends § 821.25 by revising paragraphs (a)(2)(iii) and (a)(3)(iv). These paragraphs previously stated that manufacturers must provide ''(t)he name, address, telephone number, and social security number (if available) of the patient'' receiving or using the device. In this final rule, FDA is revising these paragraphs by adding, at the end of each one, the clause ''unless not released by the patient under § 821.55(a).''

These changes conform § 821.25(a)(2)(iii) and (a)(3)(iv) of the final regulation to section 519(e)(2) of the act, as amended by FDAMA, which specifically states that patients receiving a tracked device may refuse to release, or refuse permission to release, the type of patient identifying information required under the current regulatory requirements.

G. Tracking Obligations of Persons Other Than Device Manufacturers: Distributor Requirements (§ 821.30)

17. In this final rule, FDA is amending § 821.30 by revising paragraphs (b)(3) and (c)(1)(ii) in identical fashion. FDA is changing the semicolons at the end of both regulatory requirements to commas. FDA then adds the phrase ''unless not released by the patient under § 821.55(a);'' following the comma in each requirement.

These revisions are made in the amended regulation for the reasons discussed above under item 16.

H. Confidentiality (§ 821.55)

18. FDA is adding new paragraph (a) to 821.55 for the reasons stated above under item 16, and redesignating existing paragraphs (a) and (b) as paragraphs (b) and (c), respectively.

V. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this final 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.

VI. 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) (as amended by Subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–721)), and the Unfunded Mandates Reform Act (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 the benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Unfunded Mandates Reform Act (in section 202) requires that agencies prepare an assessment of anticipated costs and benefits before proposing any expenditure by State, local, and tribal governments, in the aggregate, or by the private sector of $100 million in any one year. Under the Regulatory Flexibility Act, unless an agency certifies that a rule will not have a significant impact on a substantial number of small entities, the agency must analyze regulatory options that would minimize any significant economic impact of a rule on small entities.

Regulations implementing the tracking requirements of SMDA became effective on August 29, 1993. The purpose of device tracking is to ensure that manufacturers of certain devices establish tracking systems that will enable them to promptly locate devices in commercial distribution. Device tracking systems can reduce serious risks by facilitating patient notifications and device recalls. Manufacturers of certain devices are required to develop, document, and operate a tracking system that will allow them to quickly notify all distributors, health professionals, or patients of a recall or a serious health risk. FDAMA amends the scope of devices that may be subject to tracking requirements, and requires the agency to issue an ''order'' notifying manufacturers to adopt a tracking method. This final rule codifies the FDAMA changes by amending the 1993 regulation to give FDA greater flexibility to issue and rescind tracking orders in response to changing levels of risk.

In December 1997, FDA advised manufacturers that the tracking requirements imposed by existing FDA regulations would remain in effect until the agency notified a firm of any change in responsibilities. On February 11, 1998, FDA sent tracking orders to manufacturers of all of the device types listed in the 1993 device tracking regulation. Beginning in August 1998, FDA used its discretionary authority under FDAMA to rescind tracking orders for approximately half of these devices because it was determined that they did not have a level of risk warranting device tracking. FDA issued tracking orders to four manufacturers of two additional devices known to be associated with serious risks, i.e., dura mater implants and AAA stent grafts. In September 1999, FDA limited the scope of tracking orders for two other device types, i. e., replacement heart valves and electromechanical infusion pumps. No additional types of devices have been added to the list of tracked devices during 2000. However, in August and October 2000, FDA issued orders to three manufacturers without previous tracking systems in place, to begin tracking their own versions of devices already on the list of tracked devices, namely, replacement heart valves, continuous ventilators, and TMJ prostheses. The discussion below estimates the cost consequences attributable to these changes in the number of manufacturers tracking

devices and the list of devices required to be tracked.

A recent agency analysis projects that the cost to industry of maintaining device tracking systems will rise from approximately $40 million in 1999, to $71 million in 2006 (Ref. 1). As detailed in that analysis, this estimate accounts for the FDAMA-related changes that: (1) Add approximately $1.8 million in new annualized costs to track the additional devices for which orders were sent in December 1998, and September 1999; and (2) save industry approximately $19.2 million per year by eliminating tracking for a number of device types and by limiting the scope of another order to devices that operate electromechanically and are used outside device user facilities. Although FDAMA changed the scope of devices subject to tracking, no requirements have been added for devices that are already tracked. Therefore, the manufacturers and distributors of devices that are already being tracked will not incur additional costs as a result of this rule. The FDAMA-related changes to the 1993 list of tracked devices result in net savings to industry of approximately $17.4 million per year (i.e., $19.2 million minus $1.8 million). In the future, the total cost of industry device tracking systems may increase as devices are added or decrease as devices are rescinded. FDA could not forecast the cost or cost savings of such future actions, however, it is likely that these would be incurred at the same rate as they have since the requirements became effective in 1993.

This final rule would also reduce agency costs by bypassing rulemaking procedures each time a device is added to or removed from the tracking list. This analysis does not quantify these costs, although substantial savings are expected from this more flexible and efficient system.

FDA has reviewed this final rule and has determined it is consistent with the regulatory philosophy and principles identified in the Executive order and these two statutes. Because the costs of the final rule total less than $100 million in any one year, the final rule is not a ''significant regulatory action'' under the Executive order and FDA is not required to perform a cost benefit analysis under to the Unfunded Mandates Reform Act.

These changes have, so far, resulted in net savings to industry. However, under the total annual distribution scheme used by FDA to estimate tracking costs by manufacturers, additional costs will be incurred by manufacturers that did not previously have tracking systems in place, as follows: (1) Four manufacturers of dura mater implants and AAA stents, which were not previously tracked under SMDA provisions but which are now subject to tracking orders issued by FDA, under FDAMA, in December 1998 and December 1999; and (2) three manufacturers of replacement heart valves, continuous ventilators, and TMJ prostheses which were ordered to be tracked in August and October 2000. To implement tracking systems, these seven manufacturers would incur total average annualized costs of approximately $1,718,500.00, or approximately $245,500 per manufacturer.

According to the Department of Commerce, there are 873 establishments with fewer than 500 employees manufacturing medical and surgical equipment and they account for about $2.4 billion in shipments, or about $2.7 million in shipments per establishment (Ref. 1). Thus, $245,000 per manufacturer would be less than 1 percent of the average annual shipments of a small manufacturer of medical equipment.

Under the total annual distribution scheme used by FDA to estimate distributor costs, additional costs would only be incurred by distributors when device types not previously tracked under SMDA provisions are added by FDA order, under FDAMA provisions, to the list of devices tracked by distributors. Implanted medical devices such as dura mater implants and AAA stents usually move directly from the manufacturer to the hospital,[1] and therefore, the agency considers the hospital to be the final and only distributor in the distribution chain for implantable devices. FDA estimates that these hospital/distributors will incur average annualized costs of $66,000 to track these two additional device types under FDAMA tracking provisions. There are approximately 5,057 community hospitals in the United States.[2] If only 10 percent of these hospitals implant the estimated 22,000 units sold per year of the added devices, the average cost per hospital would be $130 per year. Based on 1997 gross revenue estimates of $564.4 billion for the 5,057 community hospitals,[3] this $130 per hospital cost would be significantly lower than 1 percent of the $111.6 million average gross revenue per hospital. Therefore, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the agency certifies that the final rule would not have a significant economic effect on a substantial number of small entities.

[1] ''From the Producer to Patient: Valuing the Medical Products Distribution Chain,'' Ernst & Whiney, prepared for the Health Industry Distributors Association, p. III–9.

[2] ''*Hospital Statistics*,'' Health Forum, an American Hospital Association Co., 1999 edition, table 3, p 8.

[3] ''*Hospital Statistics*,'' Health Forum, an American Hospital Association Co., 1999 edition, table 3, p 9.

VII. 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 order and, consequently, a federalism summary impact statement is not required.

VIII. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3502). The title, description, and respondent description of the information collection provisions are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Medical Devices; Device Tracking (Amended)

Description: FDA is amending the device tracking regulation to conform the regulation to, and implement, changes made in section 519(e)(1) and (e)(2) of the act by FDAMA.

This final rule revises the scope, removes the lists of tracked devices, and amends certain confidentiality requirements of the current medical device tracking regulation (part 821). This rule also makes certain nonsubstantive revisions in the tracking regulation to remove outdated references or to simplify terminology.

Under the revised scope of the amended tracking regulation, FDA is requiring manufacturers of class II or class III devices, including repackers, relabelers, and importers of these devices, when required by tracking orders issued by FDA for particular devices, to adopt a method of tracking the devices throughout distribution to

the device user or patient. Under patient confidentiality provisions, added to the amended regulation by this final rule, patients may refuse, or refuse permission, to release particular identification information. Though revisions of certain other requirements were made for simplification purposes, tracking requirements have not changed substantively.

Manufacturers of tracked devices, i.e., devices subject to FDA tracking orders, continue to be required by the amended regulation to gather, record, maintain, and make available during FDA inspection, and to provide within 3 or 10 working days, upon FDA request, information on the location and current users of tracked devices, and other use-related information. Upon receiving tracked devices, distributors, final distributors, and multiple distributors must continue to provide tracked device manufacturers with device identity and receipt information and, when applicable, patient identity and other related usage information.

As it was before revision by this final rule, the purpose of the tracking requirements is to facilitate manufacturers identifying the current location and identity of all persons using tracked devices, to the extent permitted by patients. With this information, manufacturers of tracked devices and FDA can expedite the recall of distributed tracked devices that are dangerous or defective.

Description of Respondents: Manufacturers, including repackers, relabelers, and importers, and distributors, final distributors, and multiple distributors involved in the manufacture and distribution of tracked devices.

FDA received one public comment on the proposed rule of April 25, 2000. On May 30, 2000, OMB approved the information collection related to the tracking of medical devices as it pertains to the previous rule approved in 1993. The approved information collection was assigned OMB control No. 0910–0442. At that time, OMB stated: ''OMB files comment on this collection as it pertains to the new proposed rule, and FDA will resubmit this collection with any changes along with the final rule. In drafting the final rule and paperwork submission, FDA should consider uses of appropriate technology (e.g. electronic submission of information) that could reduce burden.''

With respect to OMB comment, FDA notes that the proposed rule, and now the final rule, provides for broad use of electronic submission for this information collection in accordance with FDA's regulations governing electronic submission of information (21 CFR part 11). FDA addresses the minor changes in the burden from the approved information collection below.

FDA addresses the one public comment related to the tracking of infusion pumps earlier in this preamble. The comment objected to the issuance of tracking orders for a category of infusion pumps that FDA issued before the proposed rule. As explained above, FDA considers this comment beyond the scope of this rule.

TABLE 1.—ESTIMATED AVERAGE ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency of Response	Total Annual Responses	Hours per Response	Total Hours
821.2 (also 821.30(e))	4	1	4	12	48
821.25(a)	1	1	1	76	76
821.25(d)	19	1	9	2	38
821.30(a) and (b)	17,000	65	1,105,000	0.1666	184,093
821.30(c)(2)	1	1	1	28	28
821.30(d)	17,000	13	221,000	0.1666	35,497
Total					219,780

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED AVERAGE ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record	Total Hours
821.25(b)	209	41,331	8,638,179	0.2899	2,504,208
821.25(c)	209	1	209	25.49	5,328[2]
821.25(c)(3)	209	1,007	210,463	0.2899	61,013
Total					2,570,549

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Includes one-time burden of 1,584 hours.

Under OMB control No. 0910–0442, OMB approved a burden of 10,175,490 responses and 2,790,693 burden hours. At that time, there were 207 manufacturers tracking devices. In 2000, FDA ordered three manufacturers that did not previously track devices to track their devices cleared for marketing and FDA rescinded a previous tracking order issued to one firm. Therefore, 209 manufacturers currently track devices (207 previous + 3 additional - 1 rescinded). FDA has no reason to believe that the change in the number of manufacturers will result in a change in the number of devices implanted. The change will only result in differences in market share.

The PRA analysis stated in the April 2000 proposed rule remains the same except for the analysis of § 821.25(c). Accordingly, the analysis stated in the proposed rule in 65 FR 24144 at 24150 for all sections of the final rule, other than § 821.25(c) is incorporated herein.

The analysis for § 821.25(c) changes because of the additional manufacturers that received tracking orders since the publication of the April 2000 proposal. As described above, three additional manufacturers received orders, and one was rescinded, therefore the analysis of § 821.25(c) is changed by the additional manufacturers.

Under § 821.25(c), manufacturers must establish standard operating procedures (SOPs) for collecting, maintaining, and auditing tracking data. FDA estimates the three new firms would take an average of 2 staff months to plan and develop a tracking system, and 1 month to draft and implement

SOPs, including the development of audit SOPs. This amounts to 1,584 hours (3 firms x 3 months x 22 working days per month x 8 hours per day).

There would be no such burdens for 206 manufacturers that have had tracking systems in place. Manufacturers with tracking systems in place would review and/or revise their tracking system SOPs on an annual basis, expending approximately 10 percent of the amount of time spent originally in drafting the SOPs (18 hours). Over the next 3 years, 617 firms would annually revise tracking SOPs as follows: 206 firms (excludes dura mater firms) for the first year, and 209 firms (includes 3 new firms) for the second and third year. The total annual burden for revising SOPs for 3 years would amount to: 624 firms x 18 hours per firm = 11,232 hours. The annual burden would be 3,744 hours (11,232/3). Thus, the total burden for § 821.25(c) would be 5,328 hours (1,584 hours + 3,744 hours).

The information collection provisions of the final rule have been submitted to OMB for review.

Prior to the effective date of this final rule, FDA will publish in the **Federal Register** a notice announcing OMB's decision to approve, modify, or disapprove the information provisions in this final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

IX. Reference

The following reference has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. ''Cost Assessment of Medical Device Tracking,'' Economics Staff, Food and Drug Administration, 1999.

List of Subjects in 21 CFR Part 821

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, 21 CFR part 821 is amended as follows:

PART 821—MEDICAL DEVICE TRACKING REQUIREMENTS

1. The authority citation for 21 CFR part 821 continues to read as follows:

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

2. Section 821.1 is amended by revising paragraphs (a) and (b); by removing paragraph (c); and by redesignating paragraphs (d) and (e) as paragraphs (c) and (d), respectively, to read as follows:

§ 821.1 Scope.

(a) The regulations in this part implement section 519(e) of the Federal Food, Drug, and Cosmetic Act (the act), which provides that the Food and Drug Administration may require a manufacturer to adopt a method of tracking a class II or class III device, if the device meets one of the following three criteria and FDA issues an order to the manufacturer: the failure of the device would be reasonably likely to have serious adverse health consequences; or the device is intended to be implanted in the human body for more than 1 year; or the device is a life-sustaining or life-supporting device used outside a device user facility. A device that meets one of these criteria and is the subject of an FDA order must comply with this part and is referred to, in this part, as a ''tracked device.''

(b) These regulations are intended to ensure that tracked devices can be traced from the device manufacturing facility to the person for whom the device is indicated, that is, the patient. Effective tracking of devices from the manufacturing facility, through the distributor network (including distributors, retailers, rental firms and other commercial enterprises, device user facilities, and licensed practitioners) and, ultimately, to the patient is necessary for the effectiveness of remedies prescribed by the act, such as patient notification (section 518(a) of the act) or device recall (section 518(e) of the act). Although these regulations do not preclude a manufacturer from involving outside organizations in that manufacturer's device tracking effort, the legal responsibility for complying with this part rests with manufacturers who are subject to tracking orders, and that responsibility cannot be altered, modified, or in any way abrogated by contracts or other agreements.

* * * * *

§ 821.2 [Amended]

3. Section 821.2 *Exemptions and variances* is amended by removing paragraph (d).

4. Section 821.3 is amended by revising paragraphs (b) and (f) to read as follows:

§ 821.3 Definitions.

* * * * *

(b) *Importer* means the initial distributor of an imported device who is subject to a tracking order. ''Importer'' does not include anyone who only furthers the marketing, e.g., brokers, jobbers, or warehousers.

* * * * *

(f) *Device intended to be implanted in the human body for more than 1 year* means a device that is intended to be placed into a surgically or naturally formed cavity of the human body for more than 1 year to continuously assist, restore, or replace the function of an organ system or structure of the human body throughout the useful life of the device. The term does not include a device that is intended and used only for temporary purposes or that is intended for explantation in 1 year or less.

* * * * *

5. Section 821.20 is revised to read as follows:

§ 821.20 Devices subject to tracking.

(a) A manufacturer of any class II or class III device that fits within one of the three criteria within § 821.1(a) must track that device in accordance with this part, if FDA issues a tracking order to that manufacturer.

(b) When responding to premarket notification submissions and remarket approval applications, FDA will notify the sponsor by issuing an order that states that FDA believes the device meets the criteria of section 519(e)(1) of the act and, by virtue of the order, the sponsor must track the device.

6. Section 821.25 is amended by revising the introductory text of paragraph (a)(2), paragraph (a)(2)(iii), the introductory text of paragraph (a)(3), and paragraph (a)(3)(iv) to read as follows:

§ 821.25 Device tracking system and content requirements: manufacturer requirements.

(a) * * *

(2) Within 10 working days of a request from FDA for tracked devices that are intended for use by a single patient over the life of the device, after distribution to or implantation in a patient:

* * * * *

(iii) The name, address, telephone number, and social security number (if available) of the patient receiving the device, unless not released by the patient under § 821.55(a);

* * * * *

(3) Except as required by order under section 518(e) of the act, within 10 working days of a request from FDA for tracked devices that are intended for use by more than one patient, after the distribution of the device to the multiple distributor:

* * * * *

(iv) The name, address, telephone number, and social security number (if available) of the patient using the device, unless not released by the patient under § 821.55(a);

* * * * *

§ 821.30 [Amended]

7. Section 821.30 *Tracking obligations of persons other than device manufacturers: distributor requirements* is amended in paragraphs (b)(3) and (c)(1)(ii) by removing the semicolon at the end of each paragraph and by adding in its place '', unless not released by the patient under § 821.55(a);''.

8. Section 821.55 is amended by redesignating paragraphs (a) and (b) as paragraphs (b) and (c), respectively, and by adding a new paragraph (a) to read as follows:

§ 821.55 Confidentiality.

(a) Any patient receiving a device subject to tracking requirements under this part may refuse to release, or refuse permission to release, the patient's name, address, telephone number, and social security number, or other identifying information for the purpose of tracking.

* * * * *

Dated: August 23, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–3076 Filed 2–7–02; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[KY–200214; FRL–7138–5]

Approval and Promulgation of Air Quality Implementation Plans; Kentucky; Revisions to the 1-Hour Ozone Maintenance State Implementation Plan for the Paducah Area, Kentucky; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; correction.

SUMMARY: On August 20, 2001, EPA published a direct final action approving revisions to the 1-hour ozone maintenance state implementation plan (SIP) for Marshall and a portion of Livingston Counties, Kentucky (the Paducah area). Those revisions were incorporated by reference into the Kentucky SIP by adding an entry to the table ''EPA-Approved Kentucky Nonregulatory Provisions'' contained in the Code of Federal Regulations (CFR). Today's document makes corrections that affect two entries in that table.

EFFECTIVE DATE: This final rule is effective on February 8, 2002.

FOR FURTHER INFORMATION CONTACT: Lynorae Benjamin, Air Quality Modeling and Transportation Planning Section, Air Planning Branch, U.S. Environmental Protection Agency Region 4, 61 Forsyth Street, SW, Atlanta, Georgia 30303–8960, 404/562–9040, (*benjamin.lynorae@epa.gov*).

SUPPLEMENTARY INFORMATION: On August 20, 2001 (66 FR 43488), EPA published a direct final action approving revisions to the 1-hour ozone maintenance SIP for the Paducah area, Kentucky. Those revisions were incorporated by reference into the Kentucky SIP by adding the entry ''Appendix 21'' to the table ''EPA-Approved Kentucky Nonregulatory Provisions'' that is contained in 40 CFR 52.920(e). On October 23, 2001, (66 FR 53662) EPA took final action to approve negative declarations for four control techniques guideline categories for a portion of the Louisville area. These revisions were also incorporated by reference as ''Appendix 21'' to the above-mentioned table. Thus, two different revisions were mistakenly incorporated by reference as the same entry to this table. In addition, the original Paducah area maintenance plan was approved as ''Appendix 14'' of this same table. The title/subject of ''Appendix 14'' was also mistakenly identified as ''Maintenance Plan for Pudach Area.'' Today's document makes all the necessary corrections to this table by revising the entry ''Appendix 14'' as follows. The subject/title is corrected to read ''Maintenance Plan for the Paducah Area.'' The State effective date, EPA approval date, and **Federal Register** Notice cite are revised to reference the revision to the Paducah area maintenance plan that was approved in the August 20, 2001, direct final action (66 FR 43488). The entry ''Appendix 21'' will now reference only the negative declarations that were approved in the October 23, 2001, final action (66 FR 53662).

Administrative Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This action merely corrects an incorrect federal citation for a previous action and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). It does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104–4).

This action also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does not 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, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely corrects a federal citation of a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act (CAA). This action also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant.

In addition, since this action is only correcting a federal citation for a SIP submission that has already been approved by EPA, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States (U.S.). EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of