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Manager, Airspace and Rules Division.

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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: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the medical device tracking regulations. The scope of the regulation and certain patient confidentiality requirements must be amended to conform 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). FDA also proposes nonsubstantive revisions to remove outdated references or simplify terminology.

DATES: Submit written comments by July 24, 2000. See section IV of this document for the proposed effective date of a final rule based on this document. Submit written comments on the information collection requirements by May 25, 2000.

ADDRESSES: Submit written comments on the proposed rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written comments regarding the information collection requirements to the Office of Information and Regulatory Affairs Office of Management and Budget (OMB), New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

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. Background

A. The SMDA and Device Tracking Regulations

The Safe Medical Device Act of 1990 (the SMDA) (Public Law 101–629) became law on November 28, 1990. It added mandatory and discretionary device tracking provisions to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*) under new section 519(e) (21 U.S.C. 360i(e)).

As added by the SMDA, new section 519(e)(1) mandated the adoption of a method of tracking by any person registered under section 510 of the act (21 U.S.C. 360) and engaged in the manufacture of a device if its failure would be reasonably likely to have serious adverse health consequences and the device was either a permanently implantable device or a life-sustaining or life-supporting device used outside a device user facility. New section 519(e)(2) authorized FDA, in its discretion, to ''designate'' other devices that must be tracked, to protect the public health and safety.

On August 16, 1993, FDA published in the **Federal Register** (58 FR 43442) the final rule setting forth regulations governing the tracking of medical devices, as provided by the SMDA under sections 519(e)(1) and (e)(2) of the act. Elsewhere in the same **Federal Register** (58 FR 43451), FDA published a rule amending the illustrative list of those devices FDA considered subject to tracking under the mandatory criteria under section 519(e)(1) and the list of devices FDA designated as subject to tracking under section 519(e)(2). The final tracking regulations for medical devices, including the amended lists of tracked devices, went into effect on August 29, 1993, and are currently codified in part 821 of title 21 of the Code of Federal Regulations (21 CFR part 821).

B. FDAMA Tracking Provisions

FDAMA (Public Law 105–115) was enacted on November 21, 1997. Section 211 of FDAMA amended the tracking provision in section 519(e)(1) of the act and became effective on February 19, 1998. Unlike the tracking provisions under the SMDA, which required tracking for any device meeting certain criteria, FDAMA allows FDA discretion in applying tracking requirements and provides that tracking requirements can be imposed only after issuance of an order.

FDAMA authorizes FDA to issue orders that require a manufacturer to adopt a method of tracking a class II or class III device if its failure would be reasonably likely to have serious adverse health consequences, or it is intended to be implanted in the human body for more than 1 year, or it is a life-sustaining or life-supporting device used outside a device user facility. As amended by FDAMA, 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.

Section 519(e) of the act, as amended by FDAMA, provides that FDA '' may by order require a manufacturer to adopt a method of tracking.'' Such an order specifies to the manufacturer the class II or class III device(s) to be tracked. FDA interprets the discretion inherent in ''may'' to allow the agency to consider additional relevant factors in determining whether to issue a tracking order for a device that meets the criteria in amended section 519(e)(1) of the act.

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 the agency 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 (S. Rept. 108, 105th Cong., 1st sess. 37 (1997)).

II. Implementation of FDAMA Tracking Authority

A. Public Meeting/Manufacturer Notification

On December 18, 1997, FDA published a **Federal Register** notice (62 FR 66373) announcing the agency's intention to hold a public meeting on January 15, 1997, in Rockville, MD to discuss changes in medical device tracking and postmarket surveillance authorities under FDAMA. In particular, the agency was interested in discussing whether it should consider additional nonbinding factors to supplement the statutory criteria, under FDAMA, in determining whether tracking requirements should be ordered by FDA.

On December 19, 1997, FDA sent letters to manufacturers having responsibilities to track devices under section 519(e) of the act. These letters advised that FDAMA would implement important statutory changes in medical device tracking, which had been authorized previously under the SMDA. The letters noted FDA's December 18, 1997, **Federal Register** notice announcing the public meeting it would conduct on January 15, 1998, to discuss

such changes. The letters also advised that existing device 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, written and oral comments were received from consumer groups, clinicians, manufacturers, and device industry associations. These comments addressed factors FDA should consider in requiring tracking and ranged from FDA consideration of clinical management issues, and the use of alternative tracking mechanisms, to consideration of the likelihood of device failure.

B. Issuance of New Tracking Orders

On February 11, 1998, FDA issued orders to manufacturers who would be required to track their devices under section 519(e) of the act, as revised by FDAMA. The orders were issued for 28 types of devices, which the agency determined met the revised tracking criteria under FDAMA. The orders became effective on February 19, 1998, the effective date of the revised tracking provision under FDAMA. The 28 devices subject to these new orders included the 26 device types previously identified as subject to tracking under the SMDA criteria in the agency's tracking regulation at § 821.20(b)(1), (b)(2), and (c). Two device types not previously listed as subject to tracking in the regulation, namely, arterial stents and intraocular lenses, were also the subject of new tracking orders under FDAMA.

In the **Federal Register** of March 4, 1998 (63 FR 10638), FDA published a notice identifying the 28 device types subject to the orders. The notice announced, again, FDA's intention to review and reconsider the imposition of tracking requirements for these devices, in light of its discretionary authority under FDAMA, to not require the tracking of devices that meet the statutory criteria. The notice also identified 13 devices that met the statutory criteria and that were subject to the February 1998 tracking orders, but that may be removed from the tracking requirement based on other factors. Comments were solicited on which nonbinding factors should be considered in making such discretionary tracking determinations.

C. Tracking Guidance Documents and FDA Reconsideration, Rescission, and Additional Issuance of Tracking Orders

In the March 4, 1998, **Federal Register**, FDA also published a notice of availability of the guidance document entitled ''Guidance on Medical Device Tracking'' (63 FR 10640). 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 what statutory and regulatory requirements had changed, and what requirements remained the same, and represented FDA's current thinking on medical device tracking under the FDAMA amendments.

Beginning on August 26, 1998, FDA issued orders to manufacturers, rescinding the tracking orders it issued, effective February 19, 1998, for 14 types of devices manufactured by firms, including intraocular lenses and arterial stents. The agency determined, in its discretion, that these 14 device types did not warrant continued tracking based on the nonbinding factors, even though the statutory criteria were met. These nonbinding factors included: (a) The likelihood of sudden, catastrophic failure, (b) the likelihood of significant adverse clinical outcomes, and (c) the need for prompt professional intervention.

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.

In the February 12, 1999, **Federal Register**, FDA published a notice of availability of the revised final guidance document entitled ''Guidance on Medical Device Tracking'' (64 FR 7197). It replaced the previous final guidance issued on March 4, 1998. The revised final guidance of February 12, 1999, stated the agency's current thinking on manufacturer and distributor tracking responsibilities, and explained statutory and regulatory requirements that either changed or remained unchanged under medical device tracking revisions made under FDAMA.

The guidance announced on February 12, 1999, provided an updated list of devices that were subject to tracking orders. It also provided the factors, such as the likelihood of sudden, catastrophic failure or significant, adverse clinical outcomes, or the need for prompt professional intervention, that FDA may use, in addition to the statutory criteria, in deciding whether to require the tracking of a device. It mentioned, as well, FDA's December 1998 issuance of tracking orders for dura mater devices.

On September 28, 1999, FDA issued orders to manufacturers of stent grafts intended to treat abdominal aortic aneurysms, requiring them to track the devices. Upon reviewing premarket applications, the agency determined these devices meet the statutory tracking criteria of amended section 519(e), because their failure would be reasonably likely to have serious adverse health effects. On January 24, 2000, FDA issued a revised ''Guidance on Medical Device Tracking'' that identifies abdominal aortic aneurysm stent grafts as tracked devices.

Agency experience indicates that industry and other interested parties were uncertain whether ''replacement heart valves'' subject to tracking include more than one type of heart valve. 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.

There was similar uncertainty concerning which infusion pumps must be tracked. The February 1999 guidance document identified ''infusion pumps, except those designated and labeled for use exclusively for fluids with low potential risks, such as enteral feeding or anti-infectives,'' as types of pumps subject to tracking. This description caused difficulty because infusion pump labeling does not always make clear the types of fluids the pumps are intended to deliver. FDA reevaluated the tracking status of these devices and clarified, in its January 24, 2000, guidance that tracking is required only for electromechanical infusion pumps used outside device user facilities.

III. Proposed Changes in Tracking Regulation

On February 19, 1998, FDAMA amended section 519(e) of the act. By operation of statute, certain provisions in the tracking regulation, part 821, became inconsistent with the tracking requirements as revised by FDAMA. This proposed rule revises certain parts of part 821 to conform with section 519 of the act, as amended. FDA is proposing to revise 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.

In addition to changes in the proposed regulation that would reflect the changes already implemented under FDAMA, FDA proposes to simplify the regulation in a few nonsubstantive areas. These include: Removing explicit references to effective dates of provisions that have been in effect since 1993 (§ 821.1(c)); removing references to

procedures for filing petitions before August 29, 1993 (§ 821.2(d)); and substituting the simple inclusive term, ''tracked devices,'' in referring to devices intended for single use or multiple use that are subject to tracking, in place of the specific terms, ''life-sustaining or life-supporting devices used outside device user facilities'' and ''permanent implants'' (§ 821.25(a)(2) and (a)(3)).

Other than the proposed changes described above, parts of the tracking regulation that were not affected by FDAMA remain unchanged. Except for the nonsubstantive terminology change noted above, there are no proposed revisions to: The regulation's system and content requirements of tracking; the obligations of persons other than device manufacturers, such as distributors; records and inspection requirements; and record retention requirements.

Each of the revisions proposed for amending the medical devices tracking regulation is discussed in more detail below.

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

Previously, under the statutory tracking provisions of section 519(e)(1) of the act, as added by the SMDA, the scope of the tracking regulations in paragraph (a) applied the requirement to adopt a method of tracking to any person who registered under section 510 of the act as the manufacturer of a device, if the device's failure would be reasonably likely to have a serious adverse health consequence and if it was either a permanently implantable device or a life-sustaining or life-supporting device used outside a device user facility. The previous SMDA tracking provision in section 519(e)(2) also allowed the agency to require, in its discretion, tracking for any other device which did not otherwise meet the statutory tracking criteria in section 519(e)(1).

FDAMA has changed the scope of the tracking provisions in several ways, as follows:

a. The tracking provision in section 519(e) of the act does not require tracking even if the statutory criteria are met unless FDA issues an order that directs a manufacturer to track a device. Under the SMDA, devices that met the certain statutory criteria were subject to tracking automatically, even if FDA did not issue an order.

b. FDAMA allows FDA to exercise discretion in determining whether a device which meets the criteria in section 519(e) shall be tracked. SMDA did not allow FDA the discretion to excuse devices from tracking requirements if the devices met the statutory criteria.

c. Under FDAMA, the types of persons subject to tracking are no longer linked to registration requirements under section 510 of the act. As amended, the tracking provision requires manufacturers who are issued a FDA tracking order to track the device(s).

d. FDAMA also modifies the criteria by which devices may be subject to tracking. Formerly, under the SMDA's section 519(e)(1), tracked devices were those that ''the failure of which would be reasonably likely to have serious adverse health consequences and which is (A) a permanently implantable device, or (B) a sustaining or life supporting device used outside a device user facility * * *.''

Under revised section 519(e)(1) of 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 1 year, or (ii) a life sustaining or life supporting device used outside a device user facility.''

In addition, the agency may no longer designate a device as one that requires tracking to protect the public health, if the device does not meet any of the criteria for tracked devices in section 519(e) of the act. Former section 519(e)(2) under the SMDA allowed FDA discretion to order tracking for devices that did not meet statutory criteria.

FDA is proposing to revise the language in paragraph (a) of § 821.1 to conform to the amended statutory language in section 519(e) of the act. Under proposed § 821.1(a), the scope of the tracking regulation would reflect the revised statutory language in section 519(e)(1) to state tracking may only be required after certain statutory criteria are met.

2. FDA is proposing to revise 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) by FDAMA. The revised tracking requirements, as amended by FDAMA, are triggered for the manufacturer by the issuance of a FDA tracking order, not by registration requirements.

3. FDA is proposing to remove paragraph (c) from § 821.1 and to redesignate paragraphs (d) and (e) as paragraphs (c) and (d), respectively. Current § 821.1(c) was included in the final tracking regulations to clarify that the effective date for the tracking requirements under the 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.

4. FDA proposes amending § 821.2 *Exemptions and variances*, 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 all of those petitions have been responded to, there is no longer any need to include procedures relating to such petitions.

5. FDA is proposing to amend § 821.3 *Definitions*, by revising the definition of ''Importer'' in paragraph (b). ''Importer'' under the current regulation is 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 proposing to remove the current 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 to replace it with the phrase, ''subject to a tracking order.'' FDA proposes that ''Importer'' be defined as ''the initial distributor of an imported device who is subject to a tracking order.'' The remainder of the definition would be unchanged.

As explained previously, FDAMA removed the requirement that persons subject to registration requirements were automatically required to track their devices if the devices met certain criteria. The revised definition of ''importer'' reflects that tracking requirements are no longer triggered by registration requirements and that FDA must issue an order to such persons before they can be subject to tracking requirements.

6. FDA is proposing to amend § 821.3 *Definitions*, by revising the definition of ''*Permanently implantable device*'' in paragraph (f). A '' permanently implantable device'' is currently defined as:

* * * 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 only for temporary purposes or which is intended for explantation.

Under the statutory tracking criteria added by the SMDA, section 519(e)(1)(A) required the mandatory tracking of a ''permanently implantable device,'' if its failure was reasonably likely to have serious adverse health consequences. To implement this provision in the absence of further statutory clarification, FDA defined the meaning of ''permanently implantable device'' in § 821.3(f) to require such implants to ''continuously assist, restore, or replace the function of an organ system or structure of the human body'' throughout their useful life. Implanted devices intended for temporary use or explantation were not included in the meaning of the term.

The type of implanted device that may be subject to tracking under section 519(e), as amended by FDAMA, has changed and must exceed a minimum implantation time period. Under the statutory tracking criteria of FDAMA, amended section 519(e)(1)(B)(i) now provides that FDA may order the tracking of a class II or class III implanted device, only if the device ''is intended to be implanted in the human body for more than 1 year.''

FDA is proposing to revise the definition in § 821.3(f) as follows:

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 which is intended and used only for temporary purposes or which is intended for explantation in 1 year or less.

FDA is proposing to change 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.'' This revision reflects the minimum implantation time period specified by FDAMA for the type of implanted device which FDA may order to be tracked under the revised statutory criteria of section 519(e). The agency is also proposing to add the phrase, ''for more than 1 year,'' in the first sentence of the revised definition after the phrase, ''of the human body.'' At the end of the second sentence, FDA is proposing to add the phrase, ''in 1 year or less.'' These latter two revisions further incorporate into the revised definition the minimum implantation time period effected 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, FDA is proposing to retain 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.

7. FDA is proposing to amend § 821.20 *Devices subject to tracking*, by revising paragraph (a) to conform to the tracking provision of section 519(e) of the act, as amended by FDAMA. Current paragraph (a) conforms to the tracking provision that was added to the act under section 519(e) by the SMDA. It required the tracking of devices that met the statutory tracking criteria for devices in section 519(e) and also required the tracking of devices that FDA, in its discretion, designated as requiring tracking.

Proposed paragraph (a) would conform to the statutory language of the revised section 519(e) under FDAMA. Accordingly, proposed § 821.20(a) would require 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 such a device is one the failure of which would be reasonably likely to have serious adverse health consequences, or is one which is intended to be implanted in the human body for more than a year, or is one which is life-sustaining or life-supporting and used outside a device user facility, and is one which warrants tracking.

8. FDA proposes the further revision of § 821.20 Devices subject to tracking, by the removal of paragraph (b), paragraph (b)(1) and the table in (b)(1), paragraph (b)(2) and the table in paragraph (b)(2), and paragraph (c) and the table in paragraph (c).

Under the SMDA tracking provision in previous section 519(e) of the act, the manufacturer of a device was required by statute to track the device if the device met the criteria set forth in section 519(e)(1). FDA was not required to issue an order for a device included in this section. It was the manufacturer's responsibility to track devices that met the statutory criteria. Under prior section 519(e)(2), the manufacturer was also required to track any device designated by FDA to require tracking. This section required FDA to issue an order.

Current paragraph (b) of § 821.20 sets out the responsibility of manufacturers to identify whether their devices met the criteria for tracking under section 519(e)(1), as added by the SMDA, and to initiate tracking. To assist manufacturers, paragraph (b) provided guidance concerning the types of devices FDA regarded as subject to tracking under the criteria in the regulation and previous section 519(e)(1). This guidance was provided in the form of an illustrative listing of example devices. Example devices were listed for permanently implantable devices in the table under paragraph (b)(1). Example devices were listed for life-sustaining or life-supporting devices used outside device user facilities in the table under paragraph (b)(2).

Current paragraph (c) of § 821.20 sets out FDA's authority to designate devices for tracking, under section 519(e)(2) of the act, as added by the SMDA. The devices that FDA had designated, by order, under the SMDA, as subject to tracking were identified in the table under paragraph (c).

FDA is proposing to remove current § 821.20(b), (b)(1) and its table, (b)(2) and its table, and (c) and its table because they no longer reflect the criteria for tracking, or a correct list of devices subject to tracking under section 519(e), as revised by FDAMA. Under the current tracking provisions of section 519(e) (1), as amended by FDAMA, FDA is given the authority to determine whether a class II or class III device meets the criteria, in sections 519(e)(1)(A) or (B), for devices that may require tracking. This determination is no longer the responsibility of the manufacturer, as current § 821.20(b) indicates.

FDA is authorized, under the current tracking provision under FDAMA, 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. Because each manufacturer of a device requiring tracking must receive a FDA tracking order, there is no need for FDA to

provide illustrative lists of example devices, as was done in current § 821.20(b)(1) and (b)(2). Moreover, because § 821.20(c) and the table under (c) listed devices subject to tracking orders under section 519(e)(2) under SMDA criteria, that list is no longer relevant under the tracking criteria, as amended by FDAMA.

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. No useful regulatory purpose would be served by replacing, in the tracking regulation at § 821.20, previous illustrative lists of example devices requiring tracking under the SMDA, with lists of device types ordered by FDA to be tracked under FDAMA. Current manufacturers with tracking obligations have been notified by order and, therefore, do not need to look in the regulations to determine if FDA believes their devices meet the tracking criteria.

Although distributors, final distributors, and multiple distributors of tracked devices will not be provided tracking orders, as manufacturers are, FDA believes it is more expeditious and effective to keep such interested parties apprised of revisions to device types subject to tracking orders, through the use of guidance or periodic **Federal Register** notices than it is to undergo the process of changing a list in a regulation. Tracking guidance or notices will be made available to interested parties through the agency's Internet and Facts-on-Demand websites. Their availability also will be announced through the publication of **Federal Register** notices. These procedures will be followed when appropriate because of changes in the types of tracked devices or changes in the agency's current thinking. The status and identification of tracked devices has already been disseminated successfully in this fashion through **Federal Register** notices published on March 4, 1998 (63 FR 10638 and 63 FR 10640) and February 12, 1999 (64 FR 7197), and through tracking guidance documents made available through the Internet on these same dates.

9. Because of the proposed removal of current § 821.20(b), (b)(1), (b)(2) and (c), FDA is proposing to redesignate current § 821.20(d) as § 821.20(b). In proposed § 821.20(b), FDA has edited, revised, and deleted certain provisions of current § 821.20(d).

Current § 821.20(d) states: ''FDA, when responding to premarket notification (510(k)) submissions and approving premarket approval applications (PMA's), will notify the sponsor that FDA believes the device meets the criteria of section 519(e)(1) and therefore should be tracked.'' Proposed § 821.20(b) states: ''When responding to premarket notification submissions and approving premarket approval applications, FDA will notify the sponsor by issuing a tracking order that FDA believes the device meets the criteria of section 519(e)(1) of the act and, by virtue of the order, is required to be tracked.''

In revising current § 821.20(d) (proposed redesignated § 821.20(b)), FDA proposes to modify the language describing the content of 510(k) and PMA orders to accurately reflect that tracking requirements are accomplished by order under FDAMA.

10. FDA is proposing to amend § 821.25 *Device tracking system and content requirements:* manufacturer requirements, by revising the terms used in the introductory text of paragraphs (a)(2) and (a)(3) to identify the types of devices subject to requirements set out under § 821.25(a)(2)(i) through (a)(2)(vii) and 821.25(a)(3)(i) through (a)(3)(viii), respectively.

The current tracking regulation sets out different types of reporting requirements based on whether the device was: (1) Intended for single use or a permanent implant (§ 821.25(a)(2)) or (2) intended for multiple use (§ 821.25(a)(3)). In describing the types of tracked devices that were subject to the requirements in these paragraphs, the current regulation restates the statutory criteria of section 519(e) of the act, as added by the SMDA, that were used to subject devices to tracking. Accordingly, current § 821.25(a)(2) tracks the SMDA language by describing those types of devices that were subject to requirements for single patient use and implant devices as ''life-sustaining or life-supporting devices used outside a device user facility * * * and permanent implants * * *.'' Similarly, current § 821.25(a)(3) tracks the SMDA language by describing those types of devices that were subject to requirements for multiple patient use devices as ''life-sustaining or life supporting devices used outside device user facilities * * * .''

Proposed § 821.25(a)(2) and (a)(3) would not change the reporting requirements for single patient use, implants, or multiple patient use devices. Proposed § 821.25(a)(2) and (a)(3) merely would delete the descriptions of single use, implants, and multiple use devices that reflect SMDA criteria that no longer apply. Instead, proposed § 821.25(a)(2) and (a)(3) substitute a description of devices that are subject to reporting requirements that is consistent with the section 519(e) of the act criteria that were amended by FDAMA. For simplification purposes, however, FDA is choosing not to fully restate the revised FDAMA section 519(e) of the act criteria for tracked devices. Proposed § 821.25(a)(2) and (a)(3), instead, refer to devices subject to tracking as ''tracked devices.''

Accordingly, in the introductory paragraph of § 821.25(a)(2), FDA is proposing to remove the phrase, ''for life-sustaining or life-supporting devices used outside a device user facility,'' and the statement, ''and permanent implants that are tracked devices.'' In their place, FDA is proposing to substitute the phrase, ''for tracked devices.'' Similarly, in the introductory paragraph of § 821.25(a)(3), FDA is proposing to remove the phrase, ''for life-sustaining or life-supporting devices used outside device user facilities,'' and the clause, ''and that are tracked devices.'' In their place, FDA is proposing to substitute the phrase, ''for tracked devices.''

11. FDA proposes to further amend § 821.25 *Device tracking system and content requirements: manufacturer requirements*, by revising paragraphs (a)(2)(iii) and (a)(3)(iv). These sections currently state that manufacturers must provide ''(t)he name, address, telephone number, and social security number (if available) of the patient'' receiving or using the device. FDA is proposing to revise these sections by adding, at the end of each of these paragraphs, the clause, ''unless not released by the patient under § 821.55(a);''.

These proposed changes bring § 821.25(a)(2)(iii) and (a)(3)(iv) into conformance with section 519(e)(2) of the act which, as amended by FDAMA, 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.

12. FDA proposes amending § 821.30 *Tracking obligations of persons other than device manufacturers: distributor requirements* by revising paragraphs (b)(3) and (c)(1)(ii) in identical fashion. The semicolons at the end of both regulatory requirements would be changed to commas and the phrase, ''unless not released by the patient under § 821.55(a);'' would be added following the comma in each requirement. These revisions are proposed for the reasons discussed above under item 11.

13. FDA is proposing to amend § 821.55 *Confidentiality*, by redesignating current paragraphs (a) and (b) as paragraphs (b) and (c),

respectively, and by adding new paragraph (a). Proposed § 821.55(a) provides that any patient receiving a tracked device, subject to the requirements of this regulation, 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 tracking purposes. This change would incorporate the provision of section 519(e)(2) of the act, as amended by FDAMA, and discussed in section III paragraph 11 of this document previously, into the tracking regulation.

Because the agency recognized that the accuracy of information in the tracking system was dependent, to some degree, on the cooperation of persons, such as patients, who were beyond the manufacturer's control, it has stated (57 FR 10702 at 10710, March 27, 1992) that persons required to track devices would only have to demonstrate a ''good faith'' effort to collect required tracking information and document why certain information was not obtained. This same position applies to information not obtainable under section 519(e)(2) of the act and proposed § 821.55(a).

IV. Effective Date

FDA proposes that any final rule that may issue based on this proposal become effective 30 days after the date of publication of the final rule in the **Federal Register**.

V. 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.

VI. Analysis of Impacts

FDA has examined the impacts of the 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 (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 1 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 the Safe Medical Devices Act 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 a quick notification to all distributors, health professionals, or patients of a recall or the existence of a serious health risk. The Food and Drug Administration Modernization Act of 1997 (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 proposed 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 market risks. In December of 1997, FDA advised manufacturers that the tracking requirements imposed by previous FDA regulations would remain in effect until the agency notified a firm of any change in responsibilities. On February 11, 1998, FDA sent current 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. Later, FDA issued tracking orders to manufacturers of two additional devices known to be associated with serious risks and limited the scope for two other device types. The discussion below estimates the cost consequences attributable to these changes in 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 $1.0 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 limiting the scope of another device to those 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 proposed rule. The FDAMA-related changes to the 1993 list of devices result in net savings to industry of approximately $18.2 million per year (i.e., $19.2 million minus $1.0 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 proposed rule would also reduce agency costs by bypassing expensive rulemaking procedures each time a device is added to or removed from the tracking list. This analysis does not quantify these costs, although a substantial savings is expected from this more flexible and efficient system.

FDA has reviewed this proposed 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 proposed rule total less than $100 million in any one year, the proposed rule is not a ''significant regulatory action'' under the Executive Order and FDA is not required to perform a cost benefit analysis under the Unfunded Mandates Reform Act.

Although these changes have, so far, resulted in a net savings to industry, the manufacturers and distributors of the two added devices, which are both implants, will incur additional costs. The four manufacturers of these devices will incur total average annualized costs of approximately $982,000. The agency is unsure how many distributors are affected, but estimates that distributors will incur average annualized costs of $66,000. High-technology or specialty items such as implants 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. 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 proposed rule would not have a significant economic effect on a substantial number of small entities.

VII. Submission of Comments

Interested persons may, on or before July 24, 2000, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted except that individuals may submit one copy. Comments are to be identified with the docket number found in 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.

VIII. Paperwork Reduction Act of 1995

A. Summary

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3502). A description of these provisions is given 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.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Medical Devices; Device Tracking (Amended)

Description: FDA is proposing to amend 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 proposed 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 proposed rule also proposes to make certain nonsubstantive revisions in the tracking regulation to remove outdated references or to simplify terminology.

Under the proposed revised scope of the amended tracking regulation, FDA is requiring manufacturers of class II or class III devices, including repackers, relabelers, and importers of such 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 proposed additional patient confidentiality provisions, patients may refuse, or refuse permission, to release particular identification information. Though revisions of certain other requirements are proposed for simplification purposes, tracking requirements are not changed substantively.

Manufacturers of tracked devices, i.e., devices subject to FDA tracking orders, would continue to be required by the proposed 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.

The purpose of these tracking requirements, as proposed for revision, continues to be 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 estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED AVERAGE ANNUAL REPORTING 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	19	2	38
821.30(a), (b)	17,000	65	1,113,295	0.1666	185,475
821.30(c)(2)	1	1	1	28	28
821.30(d)	17,000	13	213,067	0.1666	35,497
Total					221,162

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

[1] "From Producer to Patient: Valuing the Medical Products Distribution Chain," Ernst & Whinney, 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.

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
821.25(b)	207	41,731	8,638,334	0.2899	2,504,253
821.25(c)	207	1	207	20.5	4,236[2]
821.25(c)(3)	207	1,017	210,562	0.2899	61,042
Total					2,569,531

[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.

B. Background Facts and Assumptions

1. Average Figures

Burden estimates for information collections are based on data and methods set forth in FDA's 1999 analysis, ''Cost Assessment of Medical Device Tracking,'' (Ref. 1). That analysis estimates industry costs for current device tracking systems through the year 2006 and cost savings for devices no longer tracked under FDAMA. Burdens shown in the tables 1 and 2 of this document and described elsewhere in this document, are average annual figures for the years 1999 to 2001.

2. Respondents

FDA has issued tracking orders to 207 manufacturers to track 13 types of devices intended to be implanted for more than 1 year (hereinafter referred to as ''tracked implants'') and 4 types of life-sustaining or life-supporting devices that are used outside device user facilities (hereinafter referred to as ''tracked l/s-l/s devices''). FDA estimates that some 17,000 distributors, final distributors, and multiple distributors are subject to tracking reporting requirements as follows: 171 wholesalers, electromedical equipment; 1,252 retailers, hospital equipment and supplies; 10,500 home care dealers/medical equipment rental companies (median of 6,000 to 15,000 dealer estimate); and 5,057 U.S.-community hospitals (16,980 (total) rounded to 17,000).

3. Tracked Implant Devices

Using implantation procedures data from the National Center for Health Statistics for 1993 through 1996, FDA applies a 2 percent annual growth rate to estimate number of procedures for tracked implant devices from 1997 through 2006 (Ref. 1). Table 3 of this document shows 1993 to 1996 figures, and table 4 of this document shows projections through 2001. FDA issued tracking orders for dura mater implants in December 1998 and for abdominal aortic aneurism (AAA) stent grafts in September 1999. Data for these devices are first considered in the appropriate years.

TABLE 3.—NUMBER OF IMPLANTATION PROCEDURES PER TRACKED IMPLANTS (1993 TO 1996)

Device Type	ICD[1] Number	Number of Procedures in 1993	Number of Procedures in 1994	Number of Procedures in 1995	Number of Procedures in 1996
Implantable pacemaker pulse generator	37.8	123,000	139,000	136,000	155,000
Cardiovascular permanent implantable pacemaker electrode	37.70–37.76	108,000	131,000	128,000	132,000
Replacement heart valve	35.2	58,000	54,000	61,000	69,000
Automatic implantable cardioverter/defibrillator	37.9	21,000	21,000	27,000	26,000
Implanted cerebellar stimulator	2.93	2,000	2,000	2,000	2,000
Implanted diaphragmatic/phrenic nerve stimulator	34.85	2,000	2,000	2,000	2,000
Implantable infusion pumps	86.06	7,000	7,000	6,000	9,000
Temporomandibular joint[2]	76.92	2,000	2,000	2,000	6,000
Ventricular bypass (assist) device	37.61–37.63	33,000	35,000	48,000	56,000
Dura mater	2.12	6,000	6,000	8,000	6,000
Abdominal aortic aneurysm grafts	n/a	n/a	n/a	n/a	n/a

[1] Implantable cardiodefibrillator.
[2] This product category includes: Temporomandibular joint prosthesis, glenoid fossa prosthesis, and mandibular condyle prosthesis.

Numbers of implantations correspond to numbers of distributed tracked implants. FDA assumes that tracked implants are distributed directly from manufacturers to final distributors, which are mostly hospitals.

TABLE 4.—TRACKED IMPLANTS: ESTIMATES OF ANNUAL DISTRIBUTION AND TOTAL TRACKED DEVICES (1994 TO 2001) (BASED ON IMPLANTATION PROCEDURE DATA)

End of Year	New Implants[1]	Previous Implants	Total Tracked
1994	393,000	0	393,000
1995	412,000	393,000	805,000
1996	457,000	805,000	1,262,000
1997	466,140	1,262,000	1,728,140
1998	475,463	1,728,140	2,203,603
1999[2]	491,339	2,203,603	2,694,942
2000[3]	516,166	2,694,942	3,211,108
2001	526,489	3,211,108	3,737,598

[1]Represents estimated number of tracked implants distributed annually.
[2]Estimated distribution for dura mater implants is included in 1999 to 2001, *et al.*, estimates.
[3]Estimated distribution for abdominal aortic aneurysm stent grafts is included in 2000 and 2001, et al., estimates.

4. Tracked l/s-l/s Devices

FDA uses unit shipment data and forecasts from 1992 and 1994 published sources, in combination with various growth rates (Ref. 1) to estimate annual sales/distribution of four types of tracked l/s-l/s devices. See table 5 of this document.

TABLE 5.—TRACKED LIFE-SUPPORTING DEVICES-ESTIMATED NUMBER OF UNITS (1991 TO 2001)

Year	Breathing Frequency Monitors	Continuous Ventilators	Direct Current Defibrillators and Paddles			Infusion Pumps (electromechanical only)		
	Total Units	Total Units	Alternate Care Units	Physician Office Units	Total Units	Syringe Units	Ambulatory Units	Total Units
1991	n/a	n/a	14,000	3,150	17,150	n/a	n/a	n/a
1992	n/a	n/a	17,850	3,591	21,441	n/a	n/a	n/a
1993	n/a	n/a	22,759	4,094	26,852	n/a	n/a	n/a
1994	12,200	4,300	29,017	4,667	33,684	23,600	30,900	54,500
1995	12,300	4,700	36,997	5,320	42,317	26,200	34,500	60,700
1996	12,800	5,100	47,171	6,065	53,236	29,100	37,500	66,600
1997	13,300	5,600	60,144	6,914	67,058	32,300	40,800	73,100
1998	13,900	6,200	76,683	7,882	84,565	35,700	44,100	79,800
1999	14,500	6,900	97,771	8,986	106,757	39,300	47,300	86,600
2000	15,100	7,700	124,658	10,244	134,902	43,000	50,400	93,400
2001	15,569	8,387	158,939	11,678	170,617	47,105	54,571	101,676

C. Burden Estimates

1. Under § 821.2, manufacturers, importers, or distributors, including final distributors, and multiple distributors, may request exemptions and variances from tracking requirements. These requests must meet the requirements for filing a citizen petition under § 10.30 (21 CFR 10.30). FDA's burden estimates for citizen petitions are approved under OMB control number 0910–0183.

The estimate for § 821.2 assumes requesters would need about 12 additional hours per petition to provide information not required under § 10.30, such as suitable alternative tracking methods justifying a variance. FDA has received an average of four requests a year for exemptions and variances from manufacturers, distributors, final distributors, and trade associations in behalf of such firms. Burdens for distributors, final distributors, and multiple distributors to submit variance or exemption requests, under § 821.30(e), are included in the estimate for § 821.2.

2. Section 821.25(a) requires manufacturers to adopt a tracking method that can provide, upon FDA request—within 3 working days, for all tracked devices, prior to distribution to patients, data about the distributors, within 10 working days, for tracked devices for single patient use, after distribution to patients, data about the devices, shipping, patients, use, and physicians, and within 10 working days, for tracked devices for multiple patient use, after distribution to multiple distributors, data about the devices, shipping, multiple distributors, use, patients, and physicians.

FDA has never requested such deadline disclosures. Assuming one occurrence a year, FDA estimates it would take a firm some 20 hours to provide location data for all tracked devices within 3 days, and 56 hours to identify all patients and/or multiple distributors possessing tracked devices.

3. Under § 821.25(d), manufacturers must notify FDA of distributor noncompliance with reporting requirements. FDA is unaware of receiving any such notices and assumes only repeated noncompliance would be reported. FDA believes it would receive no more than 19 notices in any year. This assumes manufacturers annually audit about 5 percent of the data reported by distributors against data base entries and that some 10 percent of audited records (approximately 19,000) might be inaccurate and require further followup. FDA believes only 0.1 percent of further audited data might represent repetitive distributor noncompliance and that it would take about 2 hours per incident to report repeated distributor noncompliance to FDA.

4. Under § 821.30(a), distributors, final distributors, and multiple distributors must report receipt related data to manufacturers, upon acquiring tracked devices. Under § 821.30(b), final distributors of tracked devices, intended to be used by a single patient over the useful life of the device, must report patient and usage related information, upon distributing the devices to patients. The agency estimates distributor reporting burdens for tracked implants and tracked l/s-l/s devices as follows:

Distributor reporting for tracked implants: Tracked implants are tracked devices intended for single patient usage. FDA assumes hospitals, for the most part, are the direct recipients of tracked implants. As final distributors, they must report both the receipt and implantation of tracked implants, but FDA believes most, in practice, make only one report to manufacturers at implantation. FDA believes most hospitals rely on manufacturer distribution records identifying initial consignees of devices, as required by the Quality System regulation (21 CFR 820.160), in lieu of reporting the receipt of tracked devices back to the manufacturers. Thus, only one report is attributed to final distributors of tracked implants in FDA's estimate.

FDA estimates it would take 10 minutes (0.1666 hours) for final distributors to report tracking data for each tracked implant distributed during the year (''new implants'' per table 4 of this document). For 1999 to 2001, the average number of ''new implants'' per year is estimated as 511,331 devices, per table 4 as follows: 491,339 devices (for 1999) + 516,166 devices (for 2000) + 526,489 devices (for 2001) ÷ 3. The average annual burden for distributor reporting for these devices would be: 511,331 (average number of ''new implants'') x 1 final distributor per device x 1 data report per final distributor x 0.1666 hours per report = 85,188 hours.

Distributor reporting for tracked l/s-l/s devices: FDA estimates there are from one to three, or a median of two, distributors or multiple distributors in distribution chains for three types of tracked l/s-l/s devices, that is, tracked breathing frequency monitors (infant apnea monitors), continuous ventilators, and direct current (DC)-defibrillators and pads. There are no final distributors for tracked l/s-l/s devices because each device is intended for multiple patient usage. Each distributor or multiple distributor would make one data report per device received during the year. See table 6 of this document for annual distribution.

For 1999 to 2001, the average number of ''total units'' (table 5 of this document) and ''new devices'' (table 6 of this document) of the above three types of tracked l/s-l/s devices distributed per year would be 160,144, as estimated per table 5 as follows: 14,500 + 6,900 + 106,757 devices (for 1999) + 15,100 + 7,700 + 134,902 devices (for 2000) + 15,569 + 8,387 + 170,617 devices (for 2001) ÷ 3. The average annual burden for distributor reporting for these three types of tracked l/s-l/s devices is estimated as: 160,144 (average number of ''new devices'') x 2 distributors or multiple distributors per device x 1 data report per distributor or multiple distributor x 0.1666 hours per report = 53,360 hours.

FDA estimates there are from one to five, or a median of three, distributors or multiple distributors in distribution chains for one type of tracked l/s-l/s device, that is, electromechanical infusion pumps that are tracked. For 1999 to 2001, the average number of ''total units'' (table 5 of this document) and ''new devices'' (table 6 of this document) of tracked electromechanical infusion pumps distributed per year would be 93,892 devices, as estimated per table 6 of this document as follows: 86,600 devices (for 1999) + 93,400 devices (for 2000) + 101,676 devices (for 2001) ÷ 3. The average annual burden for distributor reporting for this one type of tracked l/s-l/s device would be: 93,892 (average number of ''new devices'') x 3 distributors or multiple distributors x 1 data report x 0.1666 hours = 46,927 hours.

TABLE 6.—TRACKED LIFE-SUSTAINING OR LIFE SUPPORTING DEVICES—ESTIMATED DISTRIBUTION

End of Year	Breathing Frequency Monitors, Continuous Ventilators, and Defibrillators		Infusion Pumps		Percent Audited	Audits per Year
	New Devices	Average No. of Distributors/ Data Reports	New Devices	Average No. of Distributors/ Data Reports		
1994	50,184	2	54,500	3	5%	2
1995	59,317	2	60,700	3	5%	2
1996	71,136	2	66,600	3	5%	2
1997	85,958	2	73,100	3	5%	1
1998	104,665	2	79,800	3	5%	1
1999	128,157	2	86,600	3	5%	1
2000	157,702	2	93,400	3	5%	1
2001	194,572	2	101,676	3	5%	1

5. Section 821.30(c)(1) requires multiple distributors to keep written records, containing patient identity and other information, each time a tracked device is distributed to patients (or users). The required information is recorded and/or kept on a daily basis by device rental and leasing firms, and other multiple distributors, as a customary and usual business practice, for purposes of billing, inventory control, liability protection, and other fiscal accounting. Therefore, the burden hours attributed to this provision are not included in the burden estimate (5 CFR 1320.3(b)(2)).

6. Under § 821.30(c)(2), multiple distributors must provide data on current users of tracked devices, current device locations, and other information, within 5 working days of a request from a manufacturer, or within 10 working days of a request from FDA. FDA is unaware of any manufacturer making such a request, nor has the agency made such a request.

Assuming one multiple distributor receives one request in a year from both a manufacturer and FDA, the agency estimates the multiple distributor would need from 3 to 4 days, or a median of 3.5 days, to comply.

7. Section 821.30(d) requires distributors, final distributors, or multiple distributors to make available for auditing, upon a manufacturer's written request, records required under this tracking regulation. FDA is unaware of manufacturers making written audit requests. However, distributors, final distributors, and multiple distributors do incur a burden in responding to manufacturer requests to verify data under manufacturer auditing of tracking system data. FDA assumes most such data verification is accomplished by telephone during ''distributor audit responses,'' which includes responses from final distributors and multiple distributors as well.

FDA's estimate of the burden for distributor audit responses assumes: Manufacturers audit data base entries for 5 percent of tracked devices distributed; entries in tracking system data bases approximate, in number and amount, data reported by distributors (data reports); and, each audited data base entry prompts one distributor audit response. FDA estimates that all distributors will take 10 minutes (0.1666 hours) to verify data. FDA allows that 10 percent of audited data might be found noncompliant, i.e., discrepant, and would require further followup responses from distributors to confirm, correct, or update data.

Distributor audit responses for tracked implants: Certain final distributors that handle tracked implants would be asked by manufacturers to verify data for 5 percent of the total number of implants actively tracked (''total tracked'' implants in table 7 of this document= ''new implants'' + ''previous implants'' in table 4 of this document). Data for dura mater and AAA stent grafts must be audited twice a year because the devices are in the first 3 years of tracking (see 21 CFR 821.25(c)(3)). FDA adjusts for these devices by factoring in the percentage they constitute of ''total tracked'' devices (shown in table 7 of this document). Data for all other tracked implants are audited once a year.

For 1999 to 2001, the average number of ''total tracked'' implants tracked per year amounts to 3,214,549 devices, as estimated per tables 4 and 7 of this document as follows: 491,339 + 2,203,603 devices (for 1999) + 516,166 + 2,694,942 devices (for 2000) + 526,489 + 3,211,108 devices for (2001) ÷ 3. The average annual burden for distributor audit responses regarding data for tracked implants, audited once a year, is estimated as: 3,214,549 devices (average number of ''total tracked'' implants) x 1 data report per device from final distributors x 1 data base entry per data report x .05 (percentage of data base entries audited) x .996 (percentage of entries audited once a year) x 1 distributor audit response per audited record x 0.1666 hours (10 minutes) per response = 26,678 hours.

Adding 10 percent for additional responses to followup verification of noncompliant data increases the burden to 29,346 hours. Applying the above formula to the 0.37 percent (average percentage) of total tracked implants whose data are audited twice a year results in an additional 635 burden hours (includes 10 percent for additional followups).

Distributor audit responses for tracked l/s-l/s devices: Distributors and multiple distributors of three types of tracked l/s-l/s devices, that is, breathing frequency (infant apnea) monitors, continuous ventilators, and DC-defibrillators would be asked to verify audited data for these devices. Only the data for ''new devices'' distributed each year would be audited. For 1999 to 2001, the average number of ''new devices'' of these three types of tracked l/s-l/s devices would be 160,144 devices, as estimated per table 6 of this document as follows: 128,157 devices (for 1999) + 157,702 devices (for 2000) + 194,572 devices (for 2001) ÷ 3.

The average annual burden for distributor audit responses regarding data for these three types of tracked l/s-l/s devices would be: 160,144 devices (average number of ''new devices'' distributed per year) x 2 data reports per device (based on mean number of distributors or multiple distributors in distribution chains) x 1 data base entry per distributor data report x .05 (percentage of entries audited) x 1 distributor audit response per audited record x 0.1666 hours per response = 2,668 hours. Adding 10 percent for additional responses to verify

noncompliant data increases the burden to 2,935 hours.

For 1999 to 2001, the average number of ''total units''(table 5 of this document), and ''new devices'' (table 6 of this document), of tracked electromechanical infusion pumps distributed per year would be 93,892 ''new devices,'' as estimated per table 6 as follows: 86,600 devices (for 1999) + 93,400 devices (for 2000) + 101,676 devices (for 2001) ÷ 3. The average annual burden for distributor audit responses regarding data for electromechanical infusion pumps that are tracked l/s-l/s devices is estimated as: 93,892 devices (average number of ''new devices'') x 3 reports (based on mean number of distributors or multiple distributors) x 1 data base entry x .05 entries audited x 1 distributor response x 0.1666 hours = 2,346 hours. Adding 10 percent for additional followup responses by distributors increases the burden to 2,581 hours.

TABLE 7.—TRACKED IMPLANTS: ESTIMATED DISTRIBUTION AND AUDIT FREQUENCY

End of Year	Total Tracked	Percent Audited	Tracked Since 1994		Tracked Since 1999	
			Percent of Total	Audits per Year	Percent of Total	Audits per Year
1994	393,000	5%	100.0%	2	n/a	n/a
1995	805,000	5%	100.0%	2	n/a	n/a
1996	1,262,000	5%	100.0%	2	n/a	n/a
1997	1,728,140	5%	100.0%	1	n/a	n/a
1998	2,203,603	5%	100.0%	1	n/a	n/a
1999[1]	2,694,942	5%	99.8%	1	0.2%	2
2000[2]	3,211,108	5%	99.6%	1	0.4%	2
2001	3,737,598	5%	99.5%	1	0.5%	2

[1] Procedural data for dura mater is included in the 1999 through 2001 estimates.
[2] Procedural data for abdominal aortic aneurysm stent grafts is included in the 2000 through 2001 estimates.

8. Under § 821.25(b) manufacturers must maintain current tracking records in accordance with standard operating procedures (SOP's). To maintain data bases, manufacturers conduct ''transactions,'' such as receiving data from distributors (distributor data reports), registering patients, making data base entries, and auditing entries against distributor data. Audit activities are estimated separately (§ 821.25(c)(3)).

Data base for tracked implants: For this estimate, and in FDA's ''Cost Assessment'' (Ref. 1), FDA uses a consulted implant manufacturer's estimate that his firm conducts some 2.5 data base transactions at a cost of about $5 per transaction. Using a composite wage rate of $17.25 for involved personnel, each transaction costing $5 would take personnel approximately 17 minutes (0.2899 hour) to complete. For 1999 to 2001, the average number of ''total tracked'' implants actively tracked per year amounts to 3,214,549 devices, as estimated per table 7 of this document as follows: 2,694,942 devices (for 1999) + 3,211,108 devices (for 2000) + 3,737,598 devices (for 2001) ÷ 3. The average annual burden for data base transactions for tracked implants is estimated as: 3,214,549 (average number of ''total tracked'' implants) x 2.5 data base transactions per year x 0.2899 hours per transaction = 2,329,744 hours.

Data base for tracked l/s-l/s devices: For three types of tracked l/s-l/s devices, i.e., tracked breathing frequency monitors, continuous ventilators, and DC-defibrillators, the average annual burden for data base transactions would be: 160,144 devices (average number of ''new devices'' distributed per year) (128,157 devices (for 1999) + 157,702 devices (for 2000) + 194,572 devices (for 2001) ÷3, per table 6 of this document) x 2 distributors or multiple distributors per device (based on the mean number in distribution chains) x 1 data report per distributor x 1 data base transaction per report x 0.2899 hour (17 minutes) per transaction = 92,851 hours.

For one type of tracked l/s-l/s device, i.e., electromechanical infusion pumps, the average annual burden would be: 93,892 devices (average number of ''new devices'' distributed per year) (86,600 devices (for 1999) + 93,400 devices (for 2000) + 101,676 devices (for 2001) ÷ 3, per table 6) x 3 distributors or multiple distributors x 1 data report x 1 transaction x 0.2899 hour per transaction = 81,658 hours.

9. Under § 821.25(c), manufacturers must establish SOP's for collecting, maintaining, and auditing tracking data.

Two dura mater manufacturers and one AAA stent graft manufacturer would have one-time burdens. FDA estimates these three firms would take an average of two staff months to plan and develop a tracking system, and one month to draft and implement standard operating procedures (SOP's), including the development of audit SOP's. 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 204 manufacturers that have had tracking systems in place since 1993.

Manufacturers with tracking systems in place would review and/or revise their tracking system SOP's on an annual basis, expending approximately 10 percent of the amount of time spent originally in drafting the SOP's, i.e., 22 days x 8 hours per day = 18 hours. Over the 3 years, 1999 to 2001, 617 firms would annually revise tracking SOP's as follows: 204 firms (excludes dura mater firms) for 1999, 206 firms (includes 2 dura mater firms, excludes 1 AAA stent firm) for 2000, and 207 firms (includes all) for 2001. The total annual burden for revising SOP's for 3 years would amount to: 617 firms x 18 hours per firm = 11,106 hours.

For 1999 to 2001, the average total annual burden (annualized burden) would be 4,236 hours: 1, 584 hours (total one time burdens) + 11,106 hours (total annual burdens) ÷ 3 years.

10. Section 821.25(c)(3) requires that the auditing SOP of manufacturers include a quality assurance program that has audit procedures to be run for each tracked device product for the first 3 years of distribution and once a year thereafter. As discussed under § 821.30(d), FDA's burden estimate for manufacturer auditing assumes firms would audit 5 percent of records for products, based on numbers of devices actively tracked (implants) each year, or distributed (tracked l/s-l/s devices) each year. Tracking data base entries, corresponding in numbers and kind, to distributor data reports (and, for tracked implants, implanted patient reports) would be verified by phone through distributor data responses or patient contacts. FDA provides for 10 percent further followups for noncompliance, i.e., to change inaccurate or update data. Burdens are estimated for auditing data for tracked implants and tracked l/s-l/s products as follows below.

Manufacturer auditing for tracked implants: Using the same $5 per tracking ''transaction'' figure that was used for data base maintenance estimates, FDA assumes auditing transactions would take 17 minutes (0.2899 hours). Manufacturers would audit data for ''total tracked'' implants, as shown in table 7 of this document. ''Total tracked'' implants correspond to amounts actively tracked each year (''new implants'' + ''previous implants'' in table 4 of this document) and take into account devices distributed in previous years that are implanted and continue to be tracked for 8 subsequent years, the approximate lifetime of implants that FDA uses.

On average, about 99.63 percent (99.8 percent (for 1999) + 99.6 percent (for 2000) + 99.5 percent (for 2001) ÷ 3, per table 7 of this document) of the data audited (i.e. 5 percent of the total data base entries corresponding to the average number of total tracked devices for 1999 to 2001) would be audited once a year and 10 percent of this data would be further audited. On average, about .37 percent of the 5 percent of data base entries audited (the approximate amount comprised by data base entries for dura mater and AAA stents) would be audited twice.

For 1999 to 2001, the average annual burden for auditing tracked implants requiring one audit per year would be: 3,214,549 devices (average number of ''total tracked'' implants actively tracked each year) (2,694,942 devices (for 1999) + 3,211,108 devices (for 2000) + 3,737,598 devices (for 2001) ÷ 3, per table 7 of this document) x 1 final distributor data report per ''new implant'' upon implantation (or 1 implanted patient report per ''previous implant'' distributed) per data base entry x .05 (percentage of data base entries audited) x .996 (average percentage of entries audited once per year) x .2899 hours (17 minutes) per audit transaction = 46,423 hours. Adding 10 percent for followup auditing increases the burden to 51,065 hours.

Applying the above formula to data base entries for tracked implants requiring 2 audits per year (an average .0037 of total tracked devices) results in 345 hours. A 10 percent additional followup rate makes 380 burden hours.

Manufacture auditing for tracked l/s-l/s devices: For breathing frequency (infant apnea) monitors, continuous ventilator, and DC-defibrillators the data for ''new devices'' distributed each year would be audited. For 1999 to 2001, the average annual burden for these devices would be: 160,144 devices (average number of ''new devices'' distributed per year) (128,157 devices (for 1999) + 157,702 devices (for 2000) + 194,572 devices (for 2001) ÷ 3, per table 6 of this document) x 2 data reports per device (based on the mean of the number of distributors or multiple distributors in distribution chains) x 1 data base entry per distributor or multiple distributor data report x .05 (percentage of entries audited) x .2899 hours = 4,642 hours.

Adding 10 percent for additional followup results in 5,106 hours.

Applying the above formula to 93,892 electromechanical infusion pumps that are tracked l/s-l/s devices (average number of ''new devices''), having a mean of three distributors or multiple distributors, would result in 4,083 hours. A 10 percent additional audit rate makes 4,491 hours.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to send comments regarding information collection by May 25, 2000, to the Office of Information and Regulatory Affairs, OMB (address above).

IX. References

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, FDA proposes to amend part 821 to read 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 by order require a manufacturer to adopt a method of tracking a class II or class III device, the failure of which would be reasonably likely to have serious adverse health consequences, or which is intended to be implanted in the human body for more than 1 year, or which is a life-sustaining or life-supporting device used outside a device user facility. A device required by FDA order to be tracked is subject to this part and is referred to herein 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 any person for whom the device is intended 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 voided 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, i.e., 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 any device which is intended and used only for temporary purposes or which is intended for explantation in 1 year or less.

* * * * *

5. Section 821.20 is amended by revising paragraph (a), by removing paragraphs (b) and (c), by redesignating paragraph (d) as paragraph (b), and by revising newly redesignated paragraph (b) to read as follows:

§ 821.20 Devices subject to tracking.

(a) When required by a tracking order issued by FDA, a manufacturer of any class II or class III device, the failure of which would be reasonably likely to have a serious adverse health consequence, or which is intended to be implanted in the human body for more than a year, or which is life-sustaining or life-supporting and used outside a device user facility, shall track that device in accordance with this part.

(b) When responding to premarket notification submissions and approving premarket approval applications, FDA will notify the sponsor by issuing a tracking 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, is required to be tracked.

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 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 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: February 14, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–10251 Filed 4–24–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Parts 4, 5, and 7

[Notice No. 896; Re: Notice Nos. 884 and 892]

RIN 1512–AB97

Health Claims and Other Health-Related Statements in the Labeling and Advertising of Alcohol Beverages; Cancellation and Rescheduling of Public Hearings (99R–199P)

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Department of the Treasury.

ACTION: Notice of proposed rulemaking; cancellation and rescheduling of public hearings.

SUMMARY: Due to the low number of requests to present oral comments, the Bureau of Alcohol, Tobacco and Firearms (ATF) is announcing the cancellation of three public hearings that were to be held concerning health claims and other health-related statements in the labeling and advertising of alcohol beverages. In addition, the hearings scheduled for Washington, DC and San Francisco, California will be limited to two days. We are also changing the date for submission of written (or e-mail) comments.

DATES: The revised hearing dates are:

1. April 25 and April 26, 2000, 10:00 a.m. to 5 p.m., Washington, DC.

2. May 23 and May 24, 2000, 10:00 a.m. to 5 p.m., San Francisco, CA.

Written (or e-mail) comments addressing Notice Nos. 884 and 892, as well as comments addressing testimony presented at the hearings, must be received on or before June 30, 2000.

ADDRESSES: The hearing locations are:

1. Washington, DC—Washington Convention Center, 900 Ninth Street, NW., Washington, DC 20001.

2. San Francisco—Embassy Suites San Francisco Airport, 150 Anza Boulevard, Burlingame, CA 94010.

FOR FURTHER INFORMATION CONTACT: Nancy Kern or Jim Ficaretta, Regulations Division, Bureau of Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue, NW., Washington, DC 20226 (202–927–8210).

SUPPLEMENTARY INFORMATION:

Background

On February 28, 2000, ATF published a notice in the **Federal Register** (Notice No. 892; 65 FR 10434) announcing the dates and locations of five public hearings that we planned to hold concerning health claims and other health-related statements in the labeling and advertising of alcohol beverages.

The notice provided that persons wishing to testify at the hearings should submit a written notification to ATF on or before April 7, 2000. As of April 18, 2000, we had received only seven requests to testify in Atlanta; seven requests to testify in Chicago; and three requests to testify in Dallas. We do not consider that this constitutes a sufficient number of requests to justify the expense of holding these three hearings. Accordingly, we are canceling the hearings that were scheduled for Atlanta, Chicago, and Dallas. Those persons who requested to appear at these hearings have been offered several alternatives, including attending one of the remaining two scheduled hearings in Washington, DC and San Francisco, California, or submitting their written comments.

The hearings scheduled for Washington, DC and San Francisco will be limited to two days. The hearing in Washington, DC will be held on April 25 and 26, and the hearing in San Francisco will be held on May 23 and 24. The hearings in both locations will start at 10:00 a.m.

We will accept written (or e-mail) comments addressing our earlier notices on this subject, Notice No. 892 and Notice No. 884 (October 25, 1999; 64 FR 57413), as well as comments addressing testimony presented at the forthcoming hearings, until June 30, 2000. This date is approximately one month after the close of the public hearings.

Drafting Information

The author of this document is James P. Ficaretta, Regulations Division, Bureau of Alcohol, Tobacco and Firearms.

Authority and Issuance

This notice is issued under the authority of 27 U.S.C. 205.

Signed: April 19, 2000.

Bradley A. Buckles,

Director.

[FR Doc. 00–10309 Filed 4–21–00; 10:42 am]

BILLING CODE 4810–31–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 948

[WV–085–FOR]

West Virginia Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed rule; public comment period and opportunity for public hearing.

SUMMARY: OSM is announcing receipt of a proposed amendment to the West Virginia regulatory program under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The program amendment consists of changes to the West Virginia regulations (38 CSR 2) contained in House Bill 4223, and changes to the Code of West Virginia contained in Senate Bill 614. The amendments are intended to comply with the Consent Decree between the plaintiff and the West Virginia Division of Environmental Protection (WVDEP) entered on February 17, 2000, in the matter of *Bragg* v. *Robertson,* No. 2:98–636 (S.D.W.Va.).

DATES: If you submit written comments, they must be received on or before 4 p.m. (local time), on May 25, 2000. If requested, a public hearing on the proposed amendments will be held at 1 p.m. (local time), on May 22, 2000. Requests to speak at the hearing must be received by 4 p.m. (local time), on May 10, 2000.

ADDRESSES: Mail or hand-deliver your written comments and requests to speak at the hearing to Mr. Roger W. Calhoun, Director, Charleston Field Office at the address listed below.

You may review copies of the West Virginia program, the proposed amendment, a listing of any scheduled