Medical Device Tracking; Guidance for Industry and FDA Staff

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This document supersedes the Guidance on Medical Device Tracking Released on August 15, 2008.

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U.S. Department of Health and Human Services
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Center for Devices and Radiological Health (CDRH)

Director's Office
Office of Compliance

Contains Nonbinding Recommendations

Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. Alternatively, electronic comments may be submitted to Regulations.gov. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

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Contains Nonbinding Recommendations

Guidance for Industry

Medical Device Tracking; Guidance for Industry and FDA Staff

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

Introduction

The Food and Drug Administration Modernization Act (FDAMA) requires that manufacturers track certain devices when the agency orders them to do so. Tracking is intended to facilitate notification and recall in the event a device presents a serious risk to health that requires prompt attention. This revised guidance announces that Thoracic Aortic Aneurysm (TAA) stent grafts have been added to the list of devices subject to medical device tracking requirements.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe should be addressed before your device can be marketed. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to follow the guidance and address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that there is a less burdensome way to address the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document.

Guidance Information for Medical Device Tracking

The following terms are used in the tracking regulation and throughout this guidance document:

Act. The Act refers to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 et seq., as amended.

Device failure (21 CFR 821.3(d)). A device failure is the failure of a device to perform or function as intended, including any deviations from the device's performance specifications or intended use.

Distributor (21 CFR 821.3(h)). A distributor is a person who furthers the distribution of a device from the original place of manufacture to the person who makes delivery or sale to the ultimate user, i.e., the final or multiple distributor, but who does not repackage or otherwise change the container, wrapper, or labeling of the device or device package.

Distributor, final (21 CFR 821.3(i)). A final distributor is a person who distributes to the patient a tracked device intended for use by a single patient over the useful life of the device. The term includes, but is not limited to, licensed practitioners, retail pharmacies, hospitals, and other types of device user facilities.

Distributor, multiple (21 CFR 821.3(k)). A multiple distributor is a device user facility, rental company, or any other entity such as a home health care agency that distributes a life-sustaining or life-supporting device intended for use by more than one patient over the useful life of the device.

FDAMA. The Food and Drug Administration Modernization Act of 1997, which amended the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 et seq.

Importer (21 CFR 821.3(b)). An importer is the initial distributor of an imported device who is required to register under section 510 of the Act (21 USC 360), and 21 CFR 807.20 of FDA's regulations. An importer does not include anyone who only performs a service for the person who furthers the marketing, i.e., a broker, jobber, or warehouser.

Life-supporting or life-sustaining device used outside a device user facility (21 CFR 821.3(g)). A life-supporting or life-sustaining device is a device that is essential, or yields information that is essential to the restoration or continuation of a bodily function that is important to the continuation of human life. Such a device is being "used outside a device user facility" when it is used outside of a hospital, nursing home, ambulatory surgical facility, or diagnostic or outpatient treatment facility. For example, a device used in a home or a doctor's office is being used outside a device user facility.

Manufacturer (21 CFR 821.3(c)). A manufacturer is any person, including any importer (i.e., an initial distributor of an imported device), repacker, relabeler, or specifications developer, who manufactures, prepares, propagates, compounds, assembles, or processes a device or engages in any of the activities described in 21 CFR 807.3(d).

Multiple-Use Devices. A multiple-use device is intended to be used by more than one patient over the useful life of the device.

Permanently implantable device (21 CFR 821.3(f)). A permanently implantable device is a device that is intended to be placed into a surgically or naturally formed cavity of the human body for more than one 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 one year or less. (See section 519 (e) (1) (B), as amended by section 211 of FDAMA.)

Prescribing physician. A prescribing physician is the physician who implants a device or orders the use of a life-supporting or life-sustaining device for use outside a device user facility.

Physician regularly following a patient. A physician regularly following a patient is a physician who routinely sees the patient in conjunction with the use of the tracked device.

Reasonably likely. Reasonably likely means probable. For purposes of tracking, "reasonably likely" does not relate to the probability of a device failure occurring. Rather, it relates to whether a serious adverse health consequence occurs.

Serious adverse health consequence (21 CFR 821.3(e)). A serious adverse health consequence is any significant adverse experience related to a device, including events which are life-threatening or which involve permanent or long-term injury or illness.

Single-use device. A single-use device is intended for use by a single patient over the life of the device.

Useful life (21 CFR 821.60). The useful life of a device is the time that a device is in use or in distribution for use.

The Law: **Background**

The tracking provisions of section 519(e) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 USC 360i(e), were added in 1990 by the Safe Medical Devices Act (SMDA) and amended in 1997 by the Food and Drug Administration Modernization Act (FDAMA). Device tracking is intended to ensure that the Food and Drug Administration (FDA) can require a manufacturer to promptly identify product distribution information and remove a device from the market. The revisions to 519(e) by FDAMA were effective as of February 19, 1998.

Tracking augments FDA's recall authority under section 518(e) of the Act, 21 USC 360h(e), to order a mandatory recall, and FDA's authority, under section 518(a) of the Act, 21 USC 360h(a), to require notification to health professionals and patients regarding unreasonable risk of substantial harm associated with a device.

The Law: **What changed**

The tracking provisions enacted by SMDA required mandatory tracking even if FDA did not issue an order. Specifically, section 519(e), as added by SMDA, required manufacturers to track if they were registered with FDA under section 510 of the act and engaged in the manufacturer of a device if its failure would be reasonably likely to have serious adverse health consequences, and if that device was either a permanently implantable device or a life-sustaining or life-supporting device used outside a device user facility. Section 519(e)(2) also authorized FDA to "designate" other devices that must be tracked, at the agency's discretion.

FDAMA revised the tracking provisions to make tracking requirements within FDA's discretion. That is, tracking under section 519(e), as revised by FDAMA, applies only when FDA determines that the statutory criteria are met and FDA issues an order.

Statutory Criteria

Devices

Section 519(e), as revised by FDAMA, states the agency may require tracking for a class II or class III devices

(A) the failure of which would be reasonably likely to have serious adverse health consequences; or
(B) which is intended to be implanted in the human body for more than one year; or
(C) which is a life sustaining or life supporting device used outside a device user facility.

Patients

A patient that receives a tracked device may refuse to release, or refuse permission to release, their name, address, social security number, or other identifying information for the purposes of tracking.

The Tracking "Order":

FDA has issued letters to each manufacturer who currently makes and distributes a legally marketed device that must be tracked under the Act, as revised by FDAMA. A revised list of devices that currently must be tracked is provided in this document. Manufacturers were notified that these orders would take effect on February 19, 1998. An order to adopt a tracking method may also be issued by FDA for a "new" device as part of the premarket clearance process. FDA will issue an order to the sponsor of the submission when clearing a premarket notification submission (510(k)) or approving a premarket approval application (PMA). A tracking order issued as a result of a premarket review will be issued as a separate order; it will not be part of a 510(k) order or a PMA approval order.

FDA will also publish a notice in the Federal Register announcing devices that are subject to tracking, whether a new or currently marketed device. If FDA determines that a device should no longer be tracked, it will notify the manufacturer by letter and publish a notice in the Federal Register.

***The Regulation:* What did not change**

The medical device tracking regulation is published in Title 21 Code of Federal Regulations (CFR) Part 821. The final rule was originally published on August 16, 1993, and became effective on August 29, 1993. Certain provisions in the tracking regulation remain effective after the effective date of FDAMA, February 19, 1998, and certain provisions are no longer effective after that date. The device tracking requirements for exemptions and variances; system and content requirements of tracking; the obligations of persons other than device manufacturers, such as distributors; records and inspection requirements; confidentiality; and record retention requirements, remain in effect as published under the authority of SMDA. See "Tracking Requirements" section.

***The Regulation:* What did change**

FDAMA changed the scope of the agency's tracking authority and therefore changed the scope of the implementing regulations. Before, under the 1990 SMDA provisions, tracking applied to all devices that met the statutory criteria. This meant that FDA did not have to issue an order to trigger the tracking requirement. As guidance, the agency provided in the 1993 tracking regulations an illustrative list of those devices that FDA believed met the statutory criteria of "permanently implantable devices" or "life-sustaining or life-supporting devices used outside a user facility" and, therefore, should be tracked. The lists were meant

to help manufacturers determine whether they were required to track their devices. Now, FDA may by "order" require a manufacturer to track a device. There is no statutory requirement to track unless FDA has issued an order.

FDA has issued orders to manufacturers who are required to track the following implantable devices:

- Temporomandibular Joint (TMJ) prosthesis
- Glenoid fossa prosthesis
- Mandibular condyle prosthesis
- Implantable pacemaker pulse generator
- Cardiovascular permanent implantable pacemaker electrode
- Replacement heart valve (mechanical only)
- Automatic implantable cardioverter/defibrillator
- Implanted cerebellar stimulator
- Implanted diaphragmatic/phrenic nerve stimulator
- Implantable infusion pumps
- Abdominal Aortic Aneurysm (AAA) stent grafts
- Silicone gel-filled breast implants
- Cultured epidermal autografts
- Thoracic Aortic Aneurysm (TAA) stent grafts
- Transcatheter Pulmonary Valve (TPV) Prosthesis

FDA has issued orders to manufacturers who are required to track the following devices that are used outside a device user facility:

- Breathing frequency monitors
- Continuous ventilators
- Ventricular bypass (assist) device
- DC-defibrillators and paddles

FDA has discretion on whether to order tracking for devices that meet the statutory requirements or to release devices from tracking based on additional guidance factors and other relevant information that comes to the agency's attention. The following additional guidance factors may be considered to determine whether a tracking order should be issued:

A. likelihood of sudden, catastrophic failure;
B. likelihood of significant adverse clinical outcome; and
C. the need for prompt professional intervention.

The agency may add or remove devices from the list of tracked devices and may consider the additional guidance factors in conjunction with the review of premarket applications, recall data, medical device reporting, inspections, petitions, postmarket surveillance or other information coming to its attention.

The following devices that were subject to tracking orders issued by the agency in February 1998 have received subsequent orders releasing them from mandatory tracking requirements:

- Intraocular Lenses
- Vascular graft prosthesis of less than 6 millimeters diameter
- Vascular graft prosthesis of 6 millimeters and greater diameter
- Interarticular disc prosthesis (interpositional implant)
- Annuloplasty ring
- Tracheal prosthesis
- Arterial stents (used in coronary or peripherial arteries)
- Penile inflatable implant
- Silicone inflatable breast prosthesis
- Testicular prosthesis, silicone gel-filled
- Silicone gel-filled chin prosthesis
- Silicone gel-filled angel chik reflux valve
- Infusion pumps - designated and labeled for use exclusively for fluids with low potential risks, e.g., enteral feeding, anti-infectives.
- Electromechanical infusion pumps
- Dura mater

What Tracking Methods Must Do: Tracking methods must provide certain critical information about the location of a tracked device within a short time frame. Manufacturers will have 3 days to provide critical information about devices that have not yet been distributed to a patient and 10 working days for devices that have been distributed to patients.

Method may vary: No specific method of tracking is required, but manufacturers must have written standard operating procedures (SOPs) for a method of tracking that will produce the information required by regulation. FDA understands that manufacturers will have different tracking methods and procedures.

Contracting the job: Manufacturers may have an outside firm manage its tracking program, but the manufacturer is responsible for making sure the outside firm meets the tracking requirements. Manufacturers cannot alter, change or in any way avoid their tracking obligation unless FDA approves a manufacturer's written request for a variance or an exemption.

Required Tracking Information:

For all tracked devices BEFORE distribution to a patient:

Distributor Information (21 CFR 821.25(a)(1)) Available in 3 working days.

- distributor(s) name;
- distributor(s) address; and
- telephone number of distributor(s) and the device's location.

Single Use Devices (21 CFR 821.25(a)(2)) Available in 10 working days.

Manufacturers are required to obtain and maintain information regarding life sustaining or life supporting devices used outside a user facility that are intended for use by a single patient over the life of the device and for devices permanently implanted in a patient for more than one year.

Patient Information:

- device identification (lot, batch, model or serial number);
- date the device was shipped by the manufacturer;
- name, address, telephone number and social security number of the patient who received the device;
- date provided to the patient;
- name, mailing address, and telephone number of the prescribing physician;
- name, mailing address, and telephone number of the physician following the patient (if different than the prescribing physician.)
- (if applicable) the date of device explant and the name, mailing address, and telephone number of the explanting physician, the date of the patient's death, or the date that the device was returned to the manufacturer, permanently retired from use, or otherwise disposed of permanently.

Multiple-Use Devices:
(21 CFR 821.25(a)(3))

Manufacturers are not required to obtain and maintain the identity of each patient that uses a tracked device when
the device is intended to be used by more than one patient over the useful life of the device. Manufacturers must have a current record relating to the multiple distributor who has the device and must provide in 10 working days to FDA, upon request, the following information:

- lot, batch, model, or serial number of the device or other identifier necessary to provide for effective tracking of the device;
- the date the device was shipped by the manufacturer;
- the name, address, and telephone number of the multiple distributor;
- the name, address, telephone number, and social security number (if available) of the patient using the device;
- location of the device;
- date the device was provided to a patient for use;
- name, address, and telephone number of the prescribing physician; and
- if and when applicable, the date that the device was returned to the manufacturer, permanently retired from use, or otherwise disposed of permanently, e.g., remarketed..

Manufacturer's Audits:

Manufacturers must make sure their method of tracking works. Manufacturers must perform audits at 6 month intervals for the first 3 years a device is tracked, and then annually after 3 years. Audits should verify that the tracking method actually works and that the information collected is accurate. A recognized statistical sampling plan should be used, such as MIL STD 105E. Audits may be conducted through on-site visits or through some other effective way of communication with the distributors, professionals and patients involved.

(21 CFR 821.25(d))

FDA must be advised of any non-reporting parties for an appropriate follow up by the Agency when a manufacturer becomes aware of such information.

FDA Inspections:	Tracking methods are subject to FDA inspection, which may include a review of the tracking system and verification of information requirements to ensure a tracking method actually tracks a device to the end user.
Tracking Records:	Tracking records must be maintained for the useful life of the device, even if a patient is lost to follow up.
Does Tracking Ever End?	Tracking is no longer required when documentation shows that the device is returned, destroyed, explanted or the patient dies. Refurbishers or remanufactures of tracked devices that remain in domestic commercial distribution are subject to tracking requirements and should be able to ensure that the original manufacturer can promptly locate the device(s).
(21 CFR 821.2)	A manufacturer, importer, or distributor may request an exemption or variance from tracking in the form of a petition. Petitions need to be submitted in the format explained in section 10.30 of FDA's regulations. For devices with an approved PMA that are also subject to a tracking order, the need for continued tracking may be reassessed, at the sponsor's request or by the agency's initiative, 10 years from the date of the original PMA's approval.
Going Out of Business: (21 CFR 821.1(e))	A manufacturer or distributor that goes out of business is required to notify FDA at the time that it notifies any government agency, court, or supplier and must provide FDA with a complete set of its tracking records and information. If a manufacturer or distributor goes out of business and other persons acquire the right to manufacture or distribute the tracked devices, then these other persons become responsible for continuing the tracking responsibilities of the previous manufacturer or distributor. If a manufacturer or distributor ceases distribution of a tracked device but continues to do other business, then it is still responsible for the tracking of devices that it previously distributed.
Labeling:	Special labeling is not required for tracked devices; however, FDA believes that some form of identification with or on the device could be useful so recipients can easily identify the device for tracking purposes.
Distributors: General Information	Distributors, final distributors, and multiple distributors, have reporting and record keeping responsibilities, particularly multiple distributors. The responsibility for collecting, maintaining, and reporting back to the manufacturer the required information for tracked devices that they receive is effective when manufacturers distribute a device that is the subject of a tracking order. If there is any question, distributors should contact the manufacturer of the device.

Information to Report:
(21 CFR 821.30(a))

Upon purchasing or acquiring any interest in a tracked device, a distributor, final distributor, or multiple distributor must promptly report to the manufacturer the following information:

- Its name and address;
- Lot, batch, model, serial number or other device identifier;
- Date the device was received;
- Person from whom the device was received; and
- The date the device was:
  Explanted
  Out of use due to patient death (date of death)
  Returned to the distributor,
  Disposed of permanently; or
  Permanently retired from use.

A distributor must promptly notify a manufacturer that it has received a tracked device and keep whatever records necessary to respond to the manufacturer's request for information.

Kits and Systems:

A kit or system assembler is considered a distributor and must notify the manufacturer that a device has been received. Anyone who receives the kit or system should be aware it contains a tracked device. A manufacturer's original tracked device labeling should remain on the tracked device included in a kit or system.

Distributor's Records:
(21 CFR 821.30(a)

A distributor, final distributor or multiple distributor must make its tracking records available to the manufacturer of
the device, upon request. This only covers those records necessary to verify tracking information. Distributors may establish separate tracking files to keep the information separate from other commercial information.

U.S. Government as Distributor:

A tracked device under the control of the U.S. Government (civilian or military) is subject to the tracking regulation and assumes the responsibilities of a distributor, final distributor and multiple distributor.

Exports:

A device distributed outside the U.S. is not subject to tracking unless it is sold to the U.S. Government. However, manufacturers must track the device through the chain of distribution to the person or firm that physically exports the device.

A reasonable effort should be made to track implanted devices when the recipient has a foreign address.

Imports:

An initial importer distributor assumes the role of a domestic manufacturer and,

therefore, must track the device throughout its distribution in the U.S. If the foreign manufacturer acts as its own initial distributor, then the foreign manufacturer is responsible for tracking. A failure to comply with tracking requirements may cause the device to be detained at the point of entry into the U.S.

Brokers:
(21 CFR 821.3(b))

For tracking purposes, someone who does not take ownership or acquire an interest in the device, but acts as an agent for the manufacturer or the owner of the device, does not have tracking responsibilities under the tracking regulation.

Final Distributor:
(21 CFR 821.30(b))

The person or institution who owns the device, e.g., a doctor or hospital, is considered the final distributor. Final distributors must report to the manufacturer the name of the patient to whom it distributed the device and other required information.

Patient Information

- name and address of the final distributor;
- lot, batch, model, or serial number of the device or other identifier necessary to track the device;
- name, address, telephone number, and social security number (if available) of the patient receiving the device;
- date that the device was provided to the patient;
- name, mailing address, and telephone number of the prescribing physician;
- name, mailing address, and telephone number of the physician who regularly follows the patient; and
- (when applicable) the date the device was --
- explanted, with the name, mailing address, and telephone number of the explanting physician;
- out of use due to patient death (date of death);
- returned to the manufacturer;
- permanently retired from use, or permanently disposed of.

Multiple Distributor Information:
(21 CFR 821.30(c))

Multiple distributors must keep tracking records each time that a life sustaining or life supporting tracked device intended for use outside a user facility is received. The manufacturer does not need to be advised of the patient(s) using the device until the information is requested.

Records
(21 CFR 821.30(c)(1))

A multiple distributor must keep the following written records:

- lot, batch, or serial number of the device or other identifier necessary to provide for effective tracking of the device;
- name, address, telephone number, and social security number (if available) of the patient using the device;
- location of the device;
- date the device was provided to the patient using the device;

- name, address, and telephone number of the prescribing physician;
- name, address, and telephone number of the physician who regularly follows the patient; and
- (if and when applicable) the date the device was:
- returned to the manufacturer;
- permanently retired from use, or otherwise disposed of permanently.

Time Frame to Report (21 CFR 821.30(c)(2))	The multiple distributor must provide this information to a manufacturer within 5 days of a request and to FDA within 10 days of a request from FDA.
Serial Multiple Distributors	When a multiple distributor rents a device to another multiple distributor, the first multiple distributor reports as a distributor. The second multiple distributor reports receipt of the tracked device to the manufacturer and becomes the multiple distributor that tracks the device to the patient and reports the required patient information to the manufacturer within 5 working days of receiving a request from the manufacturer.
User Facilities	User facilities, such as hospitals and nursing homes, have responsibilities as a final distributor or multiple distributor, depending on whether the device is for single or multiple use. For example, a hospital engaged in the implantation of tracked devices is a final distributor of those devices; the hospital's outpatient clinic that rents, leases, or loans an infant apnea monitor is a multiple distributor of those devices.
Reporting Format	There is no obligation to use a particular reporting format, but the required information must be provided to the manufacturer. Whenever possible, hospitals should consider using the manufacturer's format to increase the ease of tracking.
Loaned Equipment (21 CFR 821.30(a))	If a user facility loaned a life sustaining or life supporting device that it had used only inside its facility, but the hospital borrowing the device permits the device to be used outside the hospital, then tracking requirements of the device may change. Life-sustaining or life-supporting devices used only in a user facility do not require tracking; however, if they are used outside the user facility, they may require tracking if they are the subject of an FDA tracking order. Examples of such devices would include continuous ventilators, breathing frequency monitors, external defibrillators, and certain infusion pumps. In that case, the manufacturer may require notification by the hospital that is borrowing the device.
Explants (21 CFR 821.30(b)(7))	Final Distributors, which include hospitals that implant devices, are responsible for providing information to the manufacturer about explants. Although a hospital that explants a device that did not implant the device has no legal responsibility to inform the manufacturer, the explanting institution should notify the manufacturer identified on the device. If the manufacturer of the explanted device cannot be identified by the device itself, the institution must make a good faith attempt to find out who the manufacturer is and report the device's explantation. If the hospital

	cannot, then a record of the explantation and attempt to identify the manufacturer should be maintained in the hospital's tracking files.
Resterilized devices	The fact that a hospital sterilized, resterilized, or repackaged a tracked device does not make the hospital a manufacturer for tracking purposes; it remains a final or multiple distributor.
Specific Device Issues:	
DC Defibrillators	Defibrillators are to be tracked to the vehicle, craft or organization that purchased the device. Tracking information does not need to extend to the patient level.
Implants	The manufacturer has the responsibility to track the implant through the chain of distribution to the patient and to update the address as necessary. How the manufacturer will update patient information should be specified in its tracking SOP.
Patient Issues:	
Patient Refusals	Patients may refuse to have their device(s) tracked. Such refusals should be documented by the product, model and serial number, and the information provided to the manufacturer. The manufacturer must maintain this record for the useful life of the device. A patient's refusal does not relieve the manufacturer of its obligation to account for the tracked device. FDA, under section 518(a) and (e) of the Act, might have to help in patient notification or recall if there were a problem with the device.
Written Patient Consent	The regulation does not require that a patient give written consent to have a device tracked or to release their identity to the manufacturer.
Patient Confidentiality (21 CFR 821.55(b))	The tracking regulation requires that the names of patients or other identifiers be provided to manufacturers or other persons subject to the tracking requirements or to a physician when the health or safety of a patient requires such disclosure and the information will not be further disclosed, pursuant to agreement.

Paperwork Reduction Act of 1995

This guidance 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. 3501-3520).

The time required to complete this information collection is estimated to average 80 hours per response, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection. Send comments regarding this burden estimate or suggestions for reducing this burden to:

Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850.