''Comments to Airspace Docket No. 00–ASO–29.'' The postcard will be date/time stamped and returned to the commenter. All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of the comments received. All comments submitted will be available for examination in the Office of the Regional Counsel for Southern Region, Room 550, 1701 Columbia Avenue, College Park, Georgia 30337, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Manager, Airspace Branch, ASO–520, Air Traffic Division, P.O. Box 20636, Atlanta, Georgia 30320. Communications must identify the docket number of this NPRM. Persons interested in being placed on a mailing list for future NPRMs should also request a copy of Advisory Circular No. 11–2A, which describes the application procedure.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR Part 71) to establish Class D airspace and Class E4 airspace at New Bern, NC. Class D airspace designations for airspace areas extending upward from the surface and Class E4 airspace designations for airspace areas designated as an extension to a Class D airspace area are published in Paragraphs 5000 and 6004 respectively, of FAA Order 7400.9G, dated September 1, 1999, and effective September 16, 1999, which is incorporated by reference in 14 CFR 71.1. The Class D and Class E4 airspace designations listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9G, Airspace Designations and Reporting Points, dated September 1, 1999, and effective September 16, 1999, is amended as follows:

Paragraph 5000 Class D Airspace

* * * * *

ASO NC D New Bern, NC [New]

Craven County Regional Airport, NC
(Lat. 35°04′23″ N, long. 77°02′35″ W)

That airspace extending upward from the surface to and including 2,600 feet MSL within a 4-mile radius of the Craven County Regional Airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

* * * * *

Paragraph 6004 Class E4 Airspace Areas Designated as an Extension to a Class D Airspace Area

* * * * *

ASO NC E4 New Bern, NC [New]

Craven County Regional Airport, NC
(Lat. 35°04′23″ N, long. 77°02′35″ W)

New Bern VOR/DME, NC

(Lat. 35°04′23″ N, long. 77°02′42″ W)

That airspace extending upward from the surface within 2.4 miles each side of the New Bern VOR/DME 038° and 210° radials, extending from the 4-mile radius to 7 miles northeast and southwest of the VOR/DME. This Class E4 airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

* * * * *

Issued in College Park, Georgia, on August 17, 2000.

Earl Newalu,

Acting Manager, Air Traffic Division, Southern Region.

[FR Doc. 00–22043 Filed 8–28–00; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 822

[Docket No. 00N–1367]

Postmarket Surveillance

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to implement the postmarket surveillance (PS) provisions of the Federal Food, Drug, and Cosmetic Act (the act), as amended by the FDA Modernization Act of 1997 (FDAMA). The purpose of this proposed rule is to provide for the collection of useful data or other information necessary to protect the public health and to provide safety and effectiveness information about devices.

DATES: Submit written comments on the proposed rule by November 27, 2000. See section III of this document for the proposed effective date of a final rule based on this document. Submit written comments regarding the information collection by September 28, 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 electronic comments and other data to http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm. For other information about filing comments electronically, see the **SUPPLEMENTARY INFORMATION** section for information on electronic access and filing address. Submit written comments on the information collection to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington,

DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: David L. Daly, Center for Devices and Radiological Health (HFZ–510), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3060.

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I. What Is the Background of This Rulemaking?

The act (21 U.S.C. 301 *et seq.*) was amended by the Medical Device Amendments of 1976 (Public Law 94–295) to give FDA broad authority over medical devices. Other laws affecting FDA's device authority under the act include the Safe Medical Devices Act of 1990 (the SMDA) (Public Law 101–629), the Medical Device Amendments of 1992 (MDA) (Public Law 102–300), and FDAMA (Public Law 105–115). The SMDA established a new provision, section 522 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360l), which was later modified by the MDA and FDAMA. This section gives FDA the authority to require manufacturers of certain medical devices to conduct postmarket surveillance. This surveillance allows for identification of potential problems with medical devices by collecting useful data that can reveal unforeseen adverse events or other information necessary to protect the public health.

FDA's decision to approve or clear a particular device is ordinarily based on limited premarket data. Even when there are premarket clinical studies, those studies typically can detect only those adverse events that are relatively frequent. PS studies can allow FDA and manufacturers to identify less common, but potentially life-threatening, device problems that were not evident during premarket development, or were noted as a potential concern that did not warrant keeping the product from reaching the market. PS establishes a way to evaluate such relatively rare events and to identify actions that may minimize patient risk, such as training, labeling, or design modification.

The act provides that FDA may require a manufacturer to conduct PS of a class II or class III device if: (1) Failure of the device would be reasonably likely to have serious adverse health consequences, (2) the device is intended to be implanted in the human body for more than 1 year, or (3) the device is intended to be life-sustaining or life-supporting and is used outside a device user facility.

A. Legislative History

Congress first granted FDA the authority to require that manufacturers of certain medical devices conduct PS with the enactment of the SMDA. They later modified this authority in FDAMA, allowing the agency more discretion in imposing PS and establishing a time limit for prospective surveillance, but leaving intact the basic authority.

The legislative history of the SMDA makes clear that the authority granted FDA under section 522 of the act to require PS of certain devices is a flexible authority that is intended to enable the agency to order manufacturers to collect data about unforeseen adverse events and other information to protect the public health. See, e.g., section 522(a) of the act (listing types of devices covered by the requirement); H. Rept. 808, 101st Cong., 2d sess., p. 32, 1990; S. Rept. 513, 101st Cong., 2d sess., p. 42, 1990.

Many problems or risks that may occur after a device is marketed cannot be detected before the device enters commerce. For a substantial majority of devices, FDA sees no clinical data before the device is commercially distributed. Section 522 of the act allows for monitoring of the earliest experience with a device once it is distributed in the general population under actual use conditions. In discussing the requirements in section 522 of the act, the House Report states that ''premarket approval cannot detect all possible problems which may occur after a device is marketed. The Committee, therefore, expects that implants and other devices critical to human health will be subject to postmarket surveillance for some appropriate period of time after they are first marketed.'' (H. Rept. 808, 101st Cong., 2d sess., p. 32, 1990).

The legislative history of the SMDA also notes weaknesses in other PS mechanisms. During passage of the SMDA, the U.S. Senate observed that the General Accounting Office (GAO) and the Office of Technology Assessment had found that reporting to FDA of potentially serious device hazards was incomplete and untimely for certain device-related injuries and malfunctions, despite FDA's mandatory medical device reporting (MDR) system. This finding was confirmed during congressional hearings. (S. Rept. 513, 101st Cong. 2d sess., p. 15, 1990.)

Although reports of device-related problems increased following the issuance of the MDR regulation (49 FR 36325, September 14, 1984), GAO found apparent under-reporting of device-related reportable events and that many firms subject to the regulation were unaware of their obligation to report device-related deaths, serious injuries, and malfunctions to FDA. GAO reported that the more serious the event, the less likely it was to be reported. GAO found that only 50 percent of class I recalls, the recall classification associated with device-related serious adverse health consequences or death, were preceded by MDR's. (PEMD–89–10, February 1989.)

In addition to the under-reporting of device-related reportable events by manufacturers, GAO concluded that problems existed with the timely receipt of information. For example, information from legislative hearings

and elsewhere shows that the manufacturer of the Bjork-Shiley 60-degree Convexo-Concave heart valve had knowledge of unexpected device failures and deficiencies in its manufacturing process. FDA did not receive timely information necessary to initiate regulatory actions promptly to protect the public or to inform those persons implanted with the heart valve of what measures should be taken to minimize their risk.

GAO also documented significant weaknesses in FDA's information gathering ability and its followup mechanisms, once information is received. The legislative history indicated a concern that FDA had not used its postmarket device authorities under section 518 of the act (21 U.S.C. 360h). These authorities empower the agency to order a notification to persons subject to a risk, and to order repair or replacement of, or reimbursement for devices. Congress attributed the agency's failure to use its authority under section 518 of the act to the agency's reluctance to assert this authority and to a weak information base that did not support aggressive regulatory action.

To address these concerns, the SMDA added a number of very important postmarket authorities to FDA's existing MDR authority, including authority to require PS for certain types of devices. In addition, the SMDA required the device industry to notify FDA of certain corrective actions, to track certain devices from the place of manufacture through the distribution chain and to the ultimate consumer, to cease distribution of a device and to notify users to cease use of the device, and to certify the number of MDR reports submitted.

In practice, the provision for mandatory surveillance contained in the SMDA was so broadly worded that it caused uncertainty about the identity of devices subject to the requirement. There was also concern that the provision for mandatory surveillance could authorize studies of indeterminate duration for devices. To address these concerns, FDAMA amended section 522 of the act to repeal mandatory surveillance, to set a presumptive limit of 3 years on studies, and to provide FDA with broad discretion to implement PS on a case-by-case basis.

B. Legal Authority

Section 522 of the act gives the agency authority to require PS of certain devices. Other provisions of the act empower FDA to implement the agency's PS authority and to monitor and enforce compliance with section 522 of the act.

Section 502(t)(3) of the act (21 U.S.C. 352(t)(3)) provides that noncompliance with requirements imposed under section 522 of the act will result in the misbranding of the device that was subject to PS. Section 301 of the act (21 U.S.C. 331) makes several actions involving misbranded devices prohibited acts, and section 301(q) specifies that noncompliance with PS and submission of false reports related to PS are prohibited acts. FDA may initiate seizure of a misbranded device under section 304 of the act (21 U.S.C. 334), and may seek injunctive, criminal, and civil relief under sections 302 and 303 of the act (21 U.S.C. 332 and 333) against individuals who commit prohibited acts.

Section 519(a) of the act (21 U.S.C. 360i(a)) gives FDA authority to issue reporting and recordkeeping requirements necessary to show a product is not misbranded. The agency is proposing to require reports and records to demonstrate that devices subject to surveillance orders comply with them and are not misbranded under 502(t) of the act.

FDA's general authority to inspect entities subject to section 522 of the act orders comes from section 704(a) of the act (21 U.S.C. 374(a)). Section 704(e) of the act authorizes the agency to inspect records required under section 519(a) of the act, including PS records that would be required by a final rule based on this proposed rule.

II. What Are the Contents of This Proposed Rule?

A. Organization and Format

The Presidential Memorandum on Plain Language issued on June 1, 1998, directed the agency to ensure that all of its documents are clear and easy to read. Part of achieving that goal involves having readers of a regulation feel that it is speaking directly to them. Therefore, the agency has attempted to incorporate plain language concepts through the use of pronouns and other plain language in this proposed rule as much as possible.

We have also organized this proposed rule to make information easier to find by grouping related sections within subparts and placing them under unnumbered, centered headings. Section headings are phrased as questions that readers, especially anyone subject to a PS order, might ask, and we have incorporated first-person personal pronouns into these headings. For example, the heading of proposed § 822.14 is, ''May I reference information previously submitted instead of submitting it again?'' The text of each section contains the answer to the question posed in the heading. Frequently, the answer is stated in terms of what ''you'' (the reader) must do. For example, the answer to ''May I reference information previously submitted instead of submitting it again?'' is, ''Yes, you may reference information that you have submitted in premarket submissions as well as other postmarket surveillance submissions. You must specify the information to be incorporated and the document number and pages where the information is located.''

We have tried to make each section of the proposed rule easy to understand by using clear and simple language rather than jargon, keeping sentences short, and using active voice rather than passive voice whenever possible. We would like your comments on how effectively we have used plain language, the organization and format of the proposed rule, and whether these have made the document clear and easy to read.

B. General

We are proposing this regulation to implement section 522 of the act, as amended by FDAMA. If a manufacturer fails to comply with requirements that FDA orders under section 522 of the act and this regulation, the device subject to the order is misbranded. In addition, the manufacturer would be committing a prohibited act under section 301(q)(1)(C) of the act by failing to comply with PS requirements.

The proposed regulation is intended to ensure that useful data or other information will be collected to address public health issues or questions related to the safety or effectiveness of devices for which the agency has issued PS orders. These issues or questions may include, among other things, the identification of unanticipated adverse events. They also may include the rate of known adverse events as the indications or conditions for use of the device change, e.g., from professional to over the counter use. We believe that the manufacturer is most likely to collect useful information through clear identification of the surveillance question(s) or issue(s) and a PS plan designed to address the question(s) or issue(s).

We have defined the following terms in § 822.3 of this proposed rule: Act, designated person, device failure, general plan guidance, investigator, life-supporting or life-sustaining device used outside a device user facility, manufacturer, postmarket surveillance,

prospective surveillance, serious adverse health consequences, specific guidance, surveillance question, and unforeseen adverse event.

Proposed § 822.4 states that the regulation applies to any manufacturer that has been ordered to conduct PS by the agency, and identifies the statutory criteria that must be met before we may order PS.

C. Notification

Section 522(a) of the act provides criteria a device must meet before we can impose PS. We may order PS of any class II or class III device if: (1) The failure of the device would be reasonably likely to have adverse health consequences, (2) the device is intended to be implanted for more than 1 year, or (3) the device is intended to be life-sustaining/life-supporting and is used outside a device user facility. This provision applies to all such devices, including devices that we review under the act, and devices (such as licensed in vitro diagnostic products) that we review under the licensing provisions of section 351 of the Public Health Service Act. In addition to the statutory criteria, we have developed additional discretionary criteria to determine when PS under section 522 of the act is an appropriate mechanism for addressing a PS question or issue. We have discussed these criteria in ''Guidance on Criteria and Approaches for Postmarket Surveillance'' (www//fda.gov/cdrh/modact/critappr.pdf). Because we will make determinations about PS on a case-by-case basis, we will notify a manufacturer in writing of the requirement to conduct PS (proposed § 822.5) as soon as we make the determination (proposed § 822.6). This may be during the review of the marketing application for the device, as the device goes to market, or after the device has been marketed for some period of time. This notification is referred to as the surveillance ''order'' and will specify the device(s) subject to the surveillance order, the reason that we are requiring PS, and any general or specific guidance that is available. We have identified the mechanisms available to appeal our decision to order PS of a particular medical device (proposed § 822.7).

We recognize that a manufacturer may have difficulty designing and submitting a PS plan to FDA within the statutory timeframe of 30 days from receipt of a surveillance order. We may, therefore, request a meeting with the affected manufacturer(s) to discuss the surveillance question and the possible approaches for the surveillance. We anticipate that this would generally occur prior to issuing a surveillance order for a particular device for the first time, and would be less likely to occur for subsequent orders for the same or similar devices. We may also request information from or meetings with manufacturers to determine whether a surveillance order is appropriate and necessary.

D. Postmarket Surveillance Plan

By law, the manufacturer must submit a plan to conduct PS within 30 days of receipt of notification of the requirement to conduct PS (the order). The manufacturer would be required to submit the original and two copies of the plan (proposed § 822.8). Under the proposed rule, foreign manufacturers will be subject to the same reporting requirements as domestic manufacturers. We believe that the inclusion of foreign manufacturers will provide information that is needed to ensure the safety of medical devices. Domestic manufacturers marketing a device for export only are also subject to the provisions of section 522(a) of the act because they are introducing the device into interstate commerce under the terms of the act.

We have identified the contents of the submission in proposed § 822.9, and the issues to be addressed in the design of the PS plan in proposed § 822.11. It is essential that the manufacturer design the plan to address the specific PS question we have identified in the order. We will include guidance to manufacturers regarding the content, preparation, and submission of PS plans in the surveillance order.

The plan must clearly describe the content and timing of interim and final reports. Each plan must outline reporting objectives, the rationale for each objective, a description of information to be reported, a description of reporting mechanisms, and proposed timeframe(s) (proposed § 822.10).

The statute requires that we determine that the person designated to conduct the surveillance has appropriate qualifications and experience. The qualifications and experience necessary will depend on the surveillance approach being used. For example, a person qualified to conduct a review and analysis of the literature and complaint files would not necessarily be qualified to conduct a prospective clinical study. Under proposed § 822.9, the plan must clearly establish the qualifications and experience of the designated person responsible for conducting the proposed surveillance.

Proposed § 822.12 identifies guidance documents available to assist a manufacturer in the preparation of a submission or the design of a PS plan. ''Guidance on Criteria and Approaches for Postmarket Surveillance'' is also available through the Center for Devices and Radiological Health (CDRH) Facts-on-Demand system and on the Internet at the CDRH website at http://www.fda.gov/cdrh/modact/critappr.pdf.

Proposed § 822.14 describes the procedure for incorporating by reference information that the manufacturer has submitted in premarket or other postmarket submissions. For example, a manufacturer may reference the description of a device that he submitted as part of the premarket notification (510(k)) submission, or the PS plan that he submitted for another device. We believe referencing information will reduce duplicative reporting, thereby reducing the burden on both the manufacturer and FDA.

Proposed § 822.15 discusses the PS period. The statute limits the prospective surveillance period to 36 months, unless FDA and the manufacturer agree to a longer period. The surveillance period is the duration of actual surveillance, not the time elapsed since the issuance of the surveillance order. If we determine that a longer period of prospective surveillance is necessary and the manufacturer does not agree, FDA and the manufacturer may employ dispute resolution under section 562 of the act (21 U.S.C. 360bbb–1). We are in the process of issuing a guidance on using dispute resolution to resolve scientific disputes concerning the regulation of medical devices.

In general, the regulations governing protection of human subjects (21 CFR part 50) and institutional review boards (IRB's) (21 CFR part 56) apply to studies of unapproved and approved products regulated by FDA. This may include PS studies, depending on the approach used. There are some approaches to PS, such as the review of published literature, where the informed consent and IRB regulations would not be applicable. For other types of studies, for example, prospective studies, the patient should be provided with the basic elements of informed consent, including the extent to which records would be kept confidential. Therefore, a manufacturer should consider the need for IRB approval and informed consent when designing a surveillance plan.

The above discussion regarding informed consent and IRB approval is not intended to preempt any State or local requirement to obtain informed consent or IRB approval. In addition, individual institutions may have requirements for informed consent and

IRB approval that apply to all researchers.

FDA does not require, nor do we generally expect, PS to result in the collection of personal identifiers. In any PS study, we expect manufacturers to ensure that the surveillance approach they use incorporates whatever measures are appropriate to protect patient privacy. Some approaches to PS, such as the review of published literature, would not require the manufacturer to take any specific steps to protect patient privacy. Moreover, many existing data bases and registries either do not capture individual identifying data or restrict access to any information that would identify an individual patient. It is unlikely, therefore, that personal identifiers will be associated with study information.

In some cases, however, we may determine that a particular PS plan requires the sponsor to take special measures to protect patient privacy. A PS plan that includes collection of personal information in identifiable form should include procedures that minimize any likelihood that patient identifiers will be transferred from the health care provider to the sponsor or any other third party except for purposes of the surveillance activity, and then only under conditions ensuring that it will be used for no other purpose.

We invite comments on the issue of informed consent for PS.

E. FDA Review and Action

In proposed § 822.16, we describe the FDA review process for PS submissions. We will first determine that the submission is administratively complete, i.e., that the manufacturer has addressed all of the elements in proposed § 822.9. We will then evaluate whether the surveillance plan is likely to result in the collection of data that will answer the surveillance question. We will evaluate the plan for scientific soundness, feasibility, and appropriateness to address the surveillance question. We will then evaluate the qualifications and experience of the person the manufacturer has designated to conduct the surveillance.

Section 522(b) of the act requires that we review PS plan submissions within 60 days of receipt (proposed § 822.17). We will notify the manufacturer in writing of the result of our review and identify any actions the manufacturer must take (proposed § 822.18). Proposed § 822.19 is a table that identifies the kinds of decisions that we may make, based on the adequacy of the PS plan, and the action that a manufacturer must take as a result of our decision. For example, if we send a manufacturer a letter stating that specific revisions or information must be submitted before we can approve the plan (an ''approvable'' letter), the manufacturer must address the concerns in the letter and submit a revised plan within the specified timeframe. We intend to use an interactive review process whenever feasible, so some revisions may be requested, made, and submitted before a final decision letter is issued.

Proposed § 822.20 describes the consequences of failure to submit a PS plan, failure to conduct surveillance in accordance with an approved plan, or failure to submit a revised plan after we disapprove a plan. Each of these failures is a failure to comply with section 522 of the act. As discussed in section I.B of this document, the failure to comply with section 522 of the act is prohibited under section 301(q) of the act. This would also mean that the device is misbranded under section 502(t)(3) of the act.

Any proposed modifications or changes in an ongoing study by the manufacturer must be submitted in writing for FDA approval prior to execution. For example, if there is a change in the designated person, the manufacturer must submit information regarding the qualifications and experience of the proposed replacement. Periods of PS under a protocol with unapproved changes may invalidate the study. Final authorization of any change rests with the agency (proposed § 822.21).

Proposed § 822.22 discusses the procedures to be followed if FDA and the manufacturer do not agree about the content of the plan or if we disapprove the plan. We anticipate that most disagreements will be resolved through a meeting with the Director of the Office of Surveillance and Biometrics, CDRH. If there are still areas of disagreement about the content of the plan, a manufacturer may use the dispute resolution process (see discussion under proposed § 822.15 above) or request a hearing under 21 CFR part 16.

Proposed § 822.23 discusses the confidentiality of the plan. Until the plan is approved, FDA considers the contents of the submission confidential. Once we approve the plan, the contents of the original submission, amendments, supplements, and reports are disclosable in accordance with the Freedom of Information Act. We will continue to protect the confidentiality of trade secret or commercial confidential information, and information identifying individual patients.

F. Responsibilities of Manufacturers

Manufacturers subject to this proposed rule must submit a plan to conduct PS within 30 days of receipt of the surveillance order (proposed § 822.24). Once the plan has been approved, the manufacturer must conduct the surveillance in accordance with the approved plan (proposed § 822.25). This means that the manufacturer must ensure that he initiates PS in a timely manner, conducts the surveillance in a scientifically sound manner, collects the data identified in the plan, and submits required reports in a timely manner. The surveillance plan and the approval order will identify timeframes for initiation of the surveillance and submission of reports.

Any change of ownership of the device results in a change of responsibility for the corresponding surveillance plan, and does not terminate it (proposed § 822.26). This applies whether the company, as a whole, changes ownership, or if only the rights to manufacture and sell the device change hands. The proposed rule contains one exception to this requirement. A manufacturer subject to this rule that is going out of business, permanently and completely, must notify FDA and discuss plans to complete or terminate PS and identify where and by whom the records will be retained (proposed § 822.27). This exception would not apply if a manufacturer ceases distribution of a device subject to PS but still continues to do any other business; under those circumstances, the manufacturer must continue to fulfill the PS requirements (proposed § 822.28).

G. Waivers and Exemptions

We recognize that there may be some circumstances where a specific requirement of this regulation may not apply or may not be feasible, given the surveillance question and the design of the PS plan. Therefore, we will consider a request for a waiver of any specific requirement of this regulation. The manufacturer may submit this request as part of the PS plan submission or separately but must include information supporting the request (proposed § 822.29).

We will consider a request for exemption from the requirement to conduct PS for a manufacturer's device or a specific model of the device. The request must explain why we should exempt the device or specific model from PS and demonstrate why the surveillance question does not apply (e.g., the device does not have the

characteristic or feature that has raised the surveillance question) or does not need to be answered. Requests for exemption should not be used to request reconsideration of our determination that PS is necessary to address a public health or safety and effectiveness issue; a manufacturer may not submit a request for a waiver or exemption in lieu of the surveillance plan.

H. Records and Reports

Proposed §§ 822.31 and 822.32 specify the records to be maintained by the manufacturer and by the investigator. These records include correspondence between FDA and the manufacturer, the manufacturer and the investigator, and between investigators; signed investigator agreements; the approved PS plan; documentation of the date and reason for any deviation from the plan; all data collected and analyses conducted for PS; and any other records required by regulation or by order. The manufacturer must retain all records for a period of 2 years after we have accepted the final report. Under some circumstances, we may require, by order, that the records be retained for a longer period of time (proposed § 822.33).

If there is a transfer of ownership or an investigator in the plan changes, the manufacturer must ensure that all records are transferred to the new manufacturer or investigator and that we are notified within 10 days of the effective date of the change. The notification must include the name, address, and telephone number of the new manufacturer or investigator and certify that all records have been transferred on the specified date (proposed § 822.34).

We will review manufacturers' PS programs during inspections. In addition, persons with PS obligations other than manufacturers, e.g., clinical investigators, will be subject to periodic inspections. Any person authorized to grant access must permit authorized FDA employees, at reasonable times and in a reasonable manner, to enter and inspect any facilities where devices are held (including any establishment where devices are packed, held, used, or implanted, or where records of results from the use of devices are kept) (proposed § 822.35).

In general, we expect manufacturers to be able to produce records required under the proposed rule within 72 hours of the initiation of an inspection (proposed § 822.36). This includes records and information required to be kept by this regulation that are in the possession of others under contract with the manufacturer to conduct the manufacturer's PS. We will state the reason or purpose for the request, and will identify to the fullest extent possible the information or type of information we are seeking. Proposed § 822.37 discusses our authority to inspect and copy records that identify subjects. Proposed § 822.38 establishes that the manufacturer must submit interim and final reports in accordance with the approved PS plan. It also specifies that we may, in accordance with section 519(a) of the act, request information or reports that are not part of the plan when we believe that it is necessary for the protection of the public health and the implementation of the act. In any such request, we will identify the information to be provided, the reason for the request, and identify how we will use the information.

III. When Will the Regulation Be Effective?

We are proposing that any final rule that may issue based on this proposed rule become effective 30 days after its date of publication in the **Federal Register**.

IV. What Is the Environmental Impact of This Regulation?

We have determined under 21 CFR 25.30(h) that this action is of a class of actions 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.

V. What Is the Economic Impact of This Regulation?

A. Introduction

We have examined the impact of the proposed rule under Executive Order 12866, 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 104–121)), and the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Executive Order 12866 directs us to assess all costs and benefits of available regulatory alternatives, and when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Section 202(a) of the UMRA requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually for inflation).

We believe that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. The proposed rule is not a significant regulatory action as defined by the Executive Order. Exercise of our PS authority could have a significant impact on a substantial number of small entities. We have included a preliminary regulatory flexibility analysis at the end of this section for comment. Finally, we have determined that the proposed rule is not a significant action as defined in the UMRA, and will not have an effect on the economy that exceeds $100 million in any one year.

B. Objectives of the Proposed Rule

The objective of the proposed rule is to enhance the public health by reducing the incidence of medical device adverse experiences. The primary problem is that we currently lack data that may reveal unforeseen adverse events relevant to the safety and effectiveness of specific devices. The proposed rule will address this concern by implementing section 522 of the act, as amended by FDAMA, to require manufacturers of specific medical devices to conduct PS. We expect PS to identify uncommon, but potentially life-threatening, device-related outcomes that were not noted during premarket development, or were noted as a continuing concern but did not warrant withholding the device from the market.

C. Risk Assessment/Baseline Conditions

In the absence of the proposed regulations, neither FDA nor device manufacturers will have complete confidence that uncommon and unforeseen events have been adequately identified for marketed devices. Currently, hundreds of medical devices are marketed each year for which failure could be reasonably likely to have serious adverse health consequences, or that are intended to be implanted in a human body for more than 1 year, or that are life-sustaining or life-supporting and used outside a device user facility. Devices with these characteristics range from implantable pacemaker pulse generators and vascular graft prostheses to dental and orthopedic implants.

Our decision to approve or clear a particular device for marketing is based on a comparison of the expected health benefits of the device to the expected risk of adverse outcomes due to device

failure. Premarket clinical studies, however, are typically designed to detect only relatively frequent adverse events. As a result, we often base premarket approval decisions on risk/benefit relationships that include only relatively frequent risks. Given this lack of complete data, neither FDA nor device manufacturers can be confident about the likelihood of serious, but infrequent, adverse events. Such events can have drastic consequences on dozens, if not hundreds of patients when a device is marketed to thousands of patients. PS provides a mechanism for gaining an early awareness and better understanding of such rare events, thus preventing further unnecessary risk to patients. Surveillance may identify actions that minimize risks, such as training, labeling, design modification, or patient selection criteria. In extreme cases, surveillance may show that the subject device should be removed from the market.

D. Costs of Postmarket Surveillance

A critical cost factor is the size of the expected surveillance. We have approved some surveillance protocols under SMDA, but rescinded most of these upon passage of FDAMA. While we cannot be precise, we estimate, based on a review of currently marketed devices, that an average of six generic device types, each with an average of five manufacturers, may be the subject of PS orders each year. This frequency would result in the initiation of 30 PS orders each year. Assuming that the duration of each PS is limited to 3 years, at any given time, 90 PS studies could be ongoing and subject to FDA review. An additional 30 PS plans would be in preliminary, design stages.

The surveillance becomes larger and more extensive as the acceptable rate of adverse events becomes smaller. Statisticians explain that if one assumes a cumulative Poisson distribution, a 0.95 probability of noting an adverse event with the incidence rate of (p) implies that the product of p and the number of observations (n) must approximately equal 3 (i.e., pn=3). For example, the surveillance must include about 30,000 observations to be 95 percent confident that a PS will detect events that occur at a frequency of 0.0001 (1 event out of 10,000 observations). The PS designed to detect more frequent events requires fewer observations. The surveillance must include about 1,500 observations to be 95 percent confident that PS will detect events that occur at a frequency of 0.002 (2 events out of 1,000 observations). We, along with device manufacturers, will need to take these considerations into account when designing PS plans.

The manufacturer would generally complete the required PS within 36 months, with at least semiannual observations. (PS utilizing literature searches may require monthly searches, although less frequent reviews may be appropriate at times.) These observations would be collected by either primary data collection from controlled clinical studies, secondary data collected from other data bases or sources (such as Medicare data bases, registries or tracking systems, and other types of studies), or published studies in the medical literature as supplemented by our current reporting systems. For purposes of this analysis, we estimate that 10 percent of the PS will require primary data collection, 50 percent may utilize secondary data sources, and 40 percent may collect adequate data from published reports. Manufacturers will incur varying costs for both design and analysis/reporting/recordkeeping phases of each surveillance in addition to the costs of data collection. In addition, we will incur costs to review the data submitted by manufacturers.

E. Design Costs

We would expect the manufacturer of each device that is subject to a PS order to develop an analysis plan for implementing the data collection. We would review and approve this plan prior to initiation. The design of a PS utilizing primary data collection would require more resources than either secondary collection or literature searches. Senior industry regulatory staff would review and approve each type of PS, however, before submission to us. For this estimate, we have assumed that the design of PS utilizing primary data collection would require 3 weeks of industry staff time, PS utilizing secondary data sources would require 2 weeks of time, and PS utilizing published literature would require only 1 staff week. According to the U.S. Bureau of Labor Statistics (1997), in 1997 the median weekly rate of compensation for managerial and professional personnel in this industry group (SIC 3841) was approximately $1,300. We have assumed an additional cost of $700 per week to account for administrative and clerical resources for a total estimate of industry resources at $2,000 per week. Therefore, the design of PS utilizing primary data collection would equal $6,000, PS utilizing secondary data collection would equal $4,000, and PS utilizing only a literature search would equal $2,000. These costs would occur prior to the first year of surveillance for each study.

F. Costs of Data Collection

1. Costs for Primary Data Collection

Primary data collection utilizing clinical trials will generally be impractical because of difficulties obtaining patient and clinician participation. In addition, this type of data collection would have significant resource requirements. Primary data could, however, be used to survey smaller populations, or populations that could experience relatively high rates of adverse events. For this analysis, we have assumed that a rigorous PS plan might call for observing 300 subjects semiannually over a 3-year period. This plan would generate 1,800 total observations and might be confidently expected to identify adverse events that occur with a frequency of 0.002, or 2 per 1,000. Moreover, patient dropouts would occur and some observations would not result in usable data, raising the number of required subjects to perhaps 350. Physicians would examine patients and provide the results of these required observations directly to manufacturers.

The costs of this data collection would be significant. While in most cases, we would not require additional procedures or tests for a patient, it is possible that some extra examinations would be required to ensure that the patient's device was still functional. In addition, normal physiologic data would likely be consistently recorded, submitted to the device manufacturers, and archived for further review. We have estimated that these data would require a direct cost of $150 per observation for the physician or medical facility to collect the data and submit it in proper form to the sponsoring manufacturer. Therefore, the cost of collecting these data would equal $300 per patient per year, or $105,000 per year. The present value of the costs of collecting these primary data over a 3-year period (using a 7 percent discount rate) is $276,000 per PS.

In addition, the patient/subject is likely to incur opportunity costs associated with being part of PS clinical studies. Because the ultimate purpose of the PS is to continue marketing the device, the patient is likely to incur costs for procedures and tests that provide him or her no direct benefit. We have estimated that such trials may require approximately 1 hour of patient time (including travel). Assuming that the opportunity cost of patients is approximately $26 per hour, the annual cost to patients of lost opportunity for PS utilizing primary data is $18,200 per year. The present value of the costs of

3 years of data collection (at 7 percent discount rate) is $48,000.

We, therefore, estimate the total present value of the costs for primary data collection to be $324,000 per PS study.

2. Costs for Secondary Data Collection

The use of secondary data for PS would not be as costly as the use of primary data. Manufacturers may obtain secondary data sets from both public and private sources, depending on the nature of the proposed surveillance, and we estimate that these data would cost approximately $50,000 per year to obtain and maintain for each surveillance. These data would include sufficient observations to ensure that infrequent events would be identified, but the expected frequency level may vary by device and patient characteristics. The present value of the costs of using secondary data sources for PS (at a 7 percent discount rate for 3 years) is $131,000.

3. Costs of Conducting Literature Searches

We believe that PS utilizing reviews of published literature and analyses of our current reporting system may require monthly collections, although less frequent reviews may be acceptable for some surveillances. As a rule, we assume that a professional employee would take approximately 3 days per month to assess published accounts and ensure that any useful data are considered. As stated earlier, the median weekly compensation rate for professional employees in this industry was approximately $1,300 in 1997. This implies that the cost of reviewing published literature would equal $780 per month for professional staff resources. Administrative and clerical support would likely add an additional $420 per month for a total cost of $1,200. Annual costs for conducting this type of PS would equal $14,400, and at a 7 percent discount rate, the present value of the costs of this data collection equals $38,000.

G. Costs of Data Analysis, Reporting, and Recordkeeping

PS is likely to entail the preparation and submission of four reports during the course of all types of surveillance: An initial report at the outset, two annual interim reports, and a final report including data analysis. In addition, manufacturers will be required to keep data available for 2 years. We assume that this category of costs is likely to be equivalent for each type of PS.

The initial and interim progress reports are expected to be relatively brief. We expect that each report would require only 1 resource week of supported professional time to be completed for a cost of $2,000 per report. The final data analysis and report would be much more extensive, and could require up to 3 months of resources to complete (statistical, medical research, legal, and senior regulatory affairs staff would likely all have input to final reports). The estimated cost of preparing and submitting a final PS report is $26,000.

We estimate that the total cost of maintaining records for 2 years after completion of the surveillance will equal $500 per year. The present value of these reporting/recordkeeping costs (at a 7 percent discount rate) equals $28,000 per surveillance.

H. Total Industry Costs of Postmarket Surveillance

The annual cost to industry for the conduct of PS is the sum of the present value of the costs of the expected studies. Each PS requiring primary data collection has a present value cost of $358,000 ($6,000 for design, $324,000 for data collection (including $48,000 of patient opportunity cost), and $28,000 for reports and recordkeeping). Each PS requiring secondary data collection has a present value cost of $163,000 ($4,000 for design, $131,000 for data collection, and $28,000 for reports and recordkeeping). Each PS requiring literature searches has a present value cost of $68,000 ($2,000 for design, $38,000 for data collection, and $28,000 for reports and recordkeeping).

We expect to issue 30 PS orders each year. We expect that 10 percent (3 PS') of these will require primary data collection. The present value of the costs for these surveillances is $1.1 million. We expect that 50 percent (15 PS') of the 30 PS orders will use secondary data collection. The present value of the costs for these surveillances is $2.4 million. The remaining 40 percent of annual PS orders (12 PS') will use literature searches. The present value of the costs for these surveillances is $0.8 million. Since we expect to issue only 30 surveillance orders each year, the annual cost to industry of this regulation is the sum of the present value costs, or $4.3 million.

I. Costs to FDA for Oversight and Review

We expect that 120 reports will be submitted each year as a result of this regulation (30 initial reports, 60 interim progress reports, and 30 final data analyses). If each report, on average, required 2 weeks of review time, we will need five review fulltime employees (FTE's) to oversee the program. We would require an additional 2.5 FTE's in support and management resources. We have estimated that the cost of each FTE is approximately $117,300. Therefore, the annual cost to FDA of maintaining PS is estimated to equal $0.9 million per year.

J. Total Annual Costs of Postmarket Surveillance

We estimate that the total annual cost for operating and maintaining a PS program is $5.2 million. Most of these costs ($4.3 million) are direct costs to manufactures while $0.9 million are our costs of operating the program.

K. Benefits of the Proposed Rule

The expected benefit of the proposed rule is the reduction in avoidable adverse events attributable to the earlier detection of potential problems. Possible outcomes of PS include withdrawal of the device from the market, changes in labeling, changes in user training, modification of the device design, or (most likely) assurance that the device does not pose an unreasonable risk to the public health. These benefits are not easily quantified because they would vary by device; but the greatest benefit would be realized when other regulatory safeguards, such as early warning through the MDR system or preproduction design controls, fail to detect and resolve serious problems. To illustrate the potential benefits of PS, we reviewed our historical records to identify and quantify the benefits of a major adverse event that could reasonably have been mitigated if this proposed rule had been in place.

L. Chronology of Historical Event

A particular type of implanted heart valve was approved and quickly accepted for patient use in 1979 because of its ability to reduce the risk of blood clots in patients. The premarket decision to approve the device considered clinical data that included an observation of one failure. The device was marketed for 8 years and implanted a total of 82,000 times. By 1999, there were 462 device failures and 300 resultant fatalities.

During the first marketing year, 5,000 patients received the device and 2 devices failed. During the second year, an additional 11,000 devices were implanted and 3 devices failed. During the third year, 14,000 devices were implanted and 7 devices failed. At this point of marketing, a total of 30,000 devices had been implanted and 12 had failed. No failures were reported in

other similar devices marketed during this period.

We believe that had PS been in effect at that time, we would have likely made this device subject to a PS order because of the noted premarket strut failure. In general, any failure to any heart valve would have been deemed serious, and potentially catastrophic. We would have been concerned about the occurrence of a strut failure during premarket testing. While this concern would not have delayed marketing approval, subsequent strut failures would have been sufficient to start the PS mechanism, if it had been available.

A likely surveillance plan would have required the manufacturer to determine the frequency of strut failures and identify contributing causes. Such a plan would have likely detected problems with the device by the end of the third year; potentially avoiding a total of 52,000 implants (82,000–30,000). Given the substantial number of patients implanted and the relatively low failure rate for the number of semiannual patient observations after 3 years (12÷102,000 = .0001), it is unlikely that the required PS would have involved the collection of primary data through prospective trials. Nevertheless, by analyzing their respective failure rates by using patient registries that would include all implanted devices, the manufacturer would have noted all complications and failures. Special attention would have been paid to all adverse events (both expected and unexpected), with special attention paid to strut fractures, early valve replacement, and deaths. Because all patients and all implants would have been entered into this registry, each occurrence of valve fracture would have been noted, and this information would have been used to determine the best course of action to protect the public health. In this case, it is likely that no valves would have been implanted in patients after the third year of marketing.

M. Postmarket Surveillance and Risk Reduction

If PS prevented 63 percent of the actual implants (52,000÷82,000), then it is likely that about 63 percent of the device failures could also have been avoided. As of 1999, the device has failed 462 times. Consequently, if the device had been removed from the market after its third year, about 293 failures would have been avoided over an 18-year period (1981 to 1999). Moreover, the 65 percent fatality rate for failures implies that the 190 fatalities associated with these 293 failures would have been avoided.

N. Value of Avoided Mortality

There are no precise methodologies for estimating the value of preventing human fatalities. Economists, however, have attempted to place a dollar value on the avoidance of fatal risks based on society's implicit willingness to pay to avoid such risks. Currently, the literature shows that $5 million may represent an approximate value of society's willingness to pay to avoid a statistical fatality. This value is reduced by an appropriate discount factor, however, to the extent that the averted fatalities would occur in future time periods.

O. Frequency of Adverse Events

To develop a possible scenario of future benefits we have assumed that, once within the next 25 years, the rule would prevent an event with characteristics identical to the heart valve incident discussed above. We cannot predict the precise year of the expected future event, but based on the past pattern of device failures, if the proposed rule identified a device with the described failure characteristics in the first year after completion of the first surveillance group (actually the fourth year of implementation), the current present value dollar benefit (assuming a 7 percent interest rate) of the avoided fatalities would be $405.5 million. If PS identified a potential device failure during the 10th project year, the present value of the dollar benefits for that event would be $270.2 million. If the device failure were not identified until the 25th year, the present value of the monetized benefits would be $97.9 million. Because we assume that, in the absence of this rule, the device failure would occur only once during the next 25 years, the likelihood of an initial failure in any 1 future year is only .04. Thus, we estimate the overall expected present value of avoiding such a future device failure at $192.0 million.

However, PS is not expected to be infallible. We have estimated that typical PS design will provide a 95 percent confidence that infrequent adverse events will be identified. Therefore, we would expect to identify potential device failures such as described 95 percent of the time. To account for this, the present value of avoiding future device failures attributable to this proposed regulation is expected to equal 95 percent of the total amount, or $182.4 million.

P. Annual Benefits of the Proposed Rule

In the illustrative case described above, we have amortized society's willingness to pay to avoid these fatalities over the evaluation period. This is because the costs of PS are ongoing and would be expended each year whether a device failure occurred or not. The current net value of avoiding these fatalities ($182.4 million), when amortized over 25 years, using a 7 percent discount rate, will result in average annualized benefits of $15.7 million.

Q. Annual Costs and Benefits of the Proposed Rule

We have estimated the annual costs of PS to equal $5.2 million. We estimated benefits based on the avoidance over the next 25 years of just one serious event to equal $15.7 million per year.

R. Small Business Analysis/Initial Regulatory Flexibility Analysis

We believe that it is likely that the proposed rule will have a significant impact on a substantial number of small entities and have conducted an initial regulatory flexibility analysis. This analysis is intended to assess the impact of the rule on small entities and to alert any potentially impacted entities of the expected impact. We request that such entities review the proposed rule and submit comments to us.

S. Description of Impact

The objective of the proposed rule is to reduce the number of adverse events associated with failure of medical devices by implementing section 522 of the act, as amended by FDAMA, to require PS of specific devices. This surveillance will be designed to identify, as early as possible, potentially dangerous but rare adverse device-related events. Our statutory authority for the proposed rule is discussed earlier in this preamble.

Makers of four categories of devices are likely to be affected by the proposed regulations: Diagnostic substances (SIC 2835), surgical and medical instruments (SIC 3841), dental equipment and supplies (SIC 3843), and ophthalmic goods (SIC 3851). This proposed rule would affect manufacturers (regardless of size) of: (1) Devices for which failure would be reasonably likely to have severe health consequences, (2) devices to be implanted in a human body for more than 1 year, and (3) devices that are life-sustaining or life-supporting outside a device user facility, because PS will likely be required for some of their currently marketed and new devices.

Manufacturers within these industry groups are typically small. Over 65 percent of the establishments in these 4 industries have 20 or fewer employees and the companies have an average of

1.09 establishments per company. Manufacturers in these industries are highly specialized, with between 83 and 98 percent of establishment sales within the affected industries. In addition, between 84 and 98 percent of diagnostic, medical, dental, and ophthalmic products are supplied by establishments within these industries. The Small Business Administration classifies as small any entity with 500 or fewer employees for all 4 industries. There is a high likelihood that manufacturers of some of the devices that would be subject to this proposed rule will include small entities.

The average company in these industries has about $9.8 million in annual revenues and about 72 employees. Based on the cost assumptions described above, any company conducting PS with primary data collection would expend 3.7 percent of annual revenues. Secondary data collection would cost an average company 1.7 percent of annual revenues. (Literature searches are not expected to impose significant costs). Because 60 percent of the expected PS orders would require significant outlays, we believe that a substantial number of small entities would be significantly affected.

We specifically solicit comment on the issue of the impact of this proposed rule on small entities.

T. Analysis of Alternatives

We examined and rejected the following alternatives to the proposed rule: (1) No action, (2) reliance on premarket approval application (PMA) annual reports, (3) increased use of PMA postapproval studies, (4) reliance on MDR reports, (5) increased educational effort to improve all reporting mechanisms, and (6) exemption of small manufacturers from PS requirements. We have rejected these alternatives at this time for the following reasons:

Alternative 1

Other sources of postmarket data or information exist, including PMA annual reports and other mechanisms. However, these sources are not always adequate to address specific postmarket issues that arise for specific devices. The proposed rule describes a process that is intended to identify sources of information available to the agency and determine their ability to address the postmarket issue prior to issuing a PS order. We would be able to meet with the affected industry sector to determine what information is currently available and whether that information may be modified to answer specific public health questions. Reliance on the current sources of postmarket data would not efficiently meet the objective of reducing avoidable adverse events.

Alternative 2

We considered increasing the requirements for data submission in PMA annual reports. This alternative was rejected because not all devices that meet the PS criteria are subject to PMA annual reports, and annual reports would not be specific enough to address issues for each type of device. In addition, the costs of requiring detailed data submissions for all affected devices would be extremely high. We rejected this alternative.

Alternative 3

If we increased postapproval studies, the expected compliance costs would be much greater, since postapproval studies generally consist of primary data collection. If a postmarket issue is identifiable at the time of approval, postapproval studies could be designed to collect meaningful data. However, if an issue would arise after FDA approval, this mechanism would not be helpful in meeting the objectives of the proposed rule. In addition, because all class II devices are marketed through premarket notification procedures, postapproval studies are not an option. We rejected this alternative.

Alternative 4

We rejected the alternative of relying on an enhanced MDR system. While MDR's are extremely important in assessing public health, it is a passive system of data collection that relies on reports from concerned professionals and manufacturers or their representatives who become aware of device problems. Often MDR reports are not specific enough to address discrete issues. We believe that the public health objectives are better met by requiring more active data collection and analysis by the responsible manufacturers of particular devices.

Alternative 5

FDA did not select the alternative of increased education in lieu of PS because any educational effort would require that FDA have sufficient information. Surveillance would be ordered to collect information that might lead to educational efforts to correct any noted problem. Thus, FDA did not believe that education alone would reduce adverse events.

Alternative 6

We rejected the alternative of exempting small device manufacturers from the proposed requirements. We recognize that surveillance would likely cause a significant impact on small entities. However, the vast majority of device manufacturers are small and any exemption would seriously reduce the effectiveness of the proposed rule. In addition, devices manufactured by small entities could as easily meet the criteria the law establishes and FDA uses to impose a PS order.

We solicit comments on any other alternatives that meet the stated objective.

U. Ensuring Small Entity Participation in Rulemaking

We believe it is possible that the proposed rule could have a significant impact on a substantial number of small entities. The impact would include the costs of conducting PS for specific devices. We solicit comments from affected entities to ensure this impact is analyzed.

The proposed rule will be available on the Internet at http://www.fda.gov for review by all interested parties and comments considered. In addition, CDRH's Division of Small Manufacturers Assistance will distribute the proposed rule through its established procedures for information dissemination during the comment period to ensure there is wide notice of the proposed rule and to solicit comments from small businesses.

VI. Conclusions

We have examined the impacts of the proposed rule implementing PS for specific medical devices. Based on these estimates, the average annual quantified benefits of $15.7 million exceed the average annualized costs of conducting surveillance ($5.2 million). These benefits assume that between three and four statistical fatalities will be avoided each year because of this proposed rule. We also expect additional benefits, not easily quantifiable, such as assurance that a marketed device does not pose an unreasonable risk to the public health and improvements in the design, labeling, and user training for devices.

We have concluded that it is likely that this rule will have a significant economic impact on a substantial number of small entities.

We solicit comment on all aspects of this analysis and all assumptions used.

VII. How Can I Comment on This Proposed Rule?

A. Electronic Access and Filing Address

You may view an electronic version of this proposed rule on the Internet at http://www.fda.gov. You may also

comment on the Internet at: http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm. Please include ''Attention: Docket No. 00N–1367'' and your name and return address in your Internet message. If you do not receive a confirmation from the system that we have received your Internet message, contact us directly at 301–827–6880. FDA is working to set up a system that would allow commenters to view already submitted comments. When this system is available, we will publish a notice in the **Federal Register**.

B. Written Comments

You may send written comments on this proposed rule electronically or by hard copy (see the **ADDRESSES** section).

All comments on the proposed rule should be specific, confined to issues pertinent to the proposed rule, and should explain the reason for any recommended change. Where possible, you should reference the specific section or paragraph of the proposal that you are addressing. FDA may not consider or include in the administrative record for the final rule comments that we receive after the close of the comment period (see the **DATES** section) or comments delivered to an address other than that listed above (see the **ADDRESSES** section).

VIII. How Does This Regulation Comply With the Paperwork Reduction Act of 1995?

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 (the PRA) (44 U.S.C. 3501–3520). A description of these provisions is given below with an estimate of the annual reporting and recordkeeping burden. The estimate includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

With respect to the following 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: Postmarket Surveillance

Description: FDA is proposing to implement the PS provisions of section 522(a) of the act, as added to the act by the SMDA and amended by FDAMA. The purpose of these proposed changes is to provide for the collection of useful data and other information necessary to protect the public health and to provide safety and effectiveness information about the device after the device is marketed. This data or information would be different from and supplemental to information collected under other provisions, such as MDR.

Description of Respondents: Manufacturers.

FDA estimates the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
822.9 and 822.10	30	1	30	120	3,600
822.21	7	1	7	40	280
822.27	1	1	1	8	8
822.28	3	1	3	40	120
822.29	5	1	5	40	200
822.30	1	1	1	120	120
822.34	5	1	5	20	100
822.38	90	2	180	80	14,400
Total					18,828

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
822.31	90	1	90	20	1,800
822.32	270	1	270	10	2,700
Total					4,500

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

FDA has had limited experience with PS under SMDA, and FDAMA significantly modified the provisions of section 522 of the act. We expect that at least some of the manufacturers will be able to satisfy the PS requirement using information or data they already have or are already collecting for other purposes. For purposes of calculating burden, however, we have assumed that each PS order can only be satisfied by a 3-year clinically-based surveillance plan, using three investigators. Based on current staffing and resources, we anticipate that we will identify surveillance issues for 6 generic devices each year. On average, 5 different manufacturers will market each of those devices, so we expect to issue 30 PS orders each year.

Each manufacturer will be required to submit a PS plan (21 CFR 822.8 and 822.10) within 30 days of the receipt of the order and interim and final reports on the progress of the surveillance (21 CFR 822.38) during the course of the surveillance. After the third year of

implementation, 30 manufacturers will complete their surveillance each year. Therefore, by year three, we will have reached a steady state, with 90 manufacturers and 270 investigators in various stages of PS each year. We anticipate that we may occasionally ask for additional information, such as distribution numbers or patterns, on a case-by-case basis. We anticipate that a small number of respondents will propose changes to their PS plans (21 CFR 822.21), request a waiver of a specific requirement of this regulation (21 CFR 822.29), or request exemption from the requirement to conduct PS of their device (21 CFR 822.30). Our experience has shown that a few respondents will go out of business (21 CFR 822.27) or cease marketing the device subject to PS (21 CFR 822.28) each year. In addition, manufacturers must certify transfer of records if the sponsor or the investigator in the plan changes (21 CFR 822.34). We anticipate that this will apply to a small number of respondents.

The regulations in 21 CFR 822.26 do not constitute information collection subject to review under the PRA because ''it entails no burden other than that necessary to identify the respondent, the date, the respondent's address, and the nature of the instrument'' (21 CFR 1320.3(h)(1)).

In compliance with section 3507(d) of the PRA, we have submitted the information collection requirements of this proposed rule to OMB for review. Interested persons are requested to send comments regarding information collection by September 28, 2000, to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

List of Subjects in 21 CFR Part 822

Postmarket surveillance, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 822 be added to read as follows:

PART 822—POSTMARKET SURVEILLANCE

Subpart A—General Provisions

Sec.
822.1 What does this part cover?
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822.3 How do you define the terms used in this part?
822.4 Does this part apply to me?

Subpart B—Notification

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822.21 What must I do if I want to make changes to my postmarket surveillance plan after you have approved it?
822.22 What recourse do I have if I do not agree with your decision?
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822.24 What are my responsibilities once I am notified that I am required to conduct postmarket surveillance?
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822.26 If my company changes ownership, what must I do?
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Subpart F—Waivers and Exemptions

822.29 May I request a waiver of a specific requirement of this part?
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Subpart G—Records and Reports

822.31 What records am I required to keep?
822.32 What records are the investigators in my surveillance plan required to keep?
822.33 How long must we keep the records?
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822.35 Can FDA inspect my manufacturing site or other sites involved in my postmarketing surveillance plan?
822.36 Can FDA inspect and copy the records related to my postmarket surveillance plan?
822.37 Under what circumstances would FDA inspect records identifying subjects?
822.38 What reports must I submit to FDA?

Authority: 21 U.S.C. 331, 352, 360l, 330l, 371.

Subpart A—General Provisions

§ 822.1 What does this part cover?

This part implements section 522 of the Federal Food, Drug, and Cosmetic Act (the act) by providing procedures and requirements for postmarket surveillance of certain types of devices. If you fail to comply with requirements FDA orders under section 522 of the act and this part, your device is considered misbranded under section 502(t)(2) of the act and you are in violation of section 301(q)(1)(C) of the act.

§ 822.2 What is the purpose of this part?

This purpose of this part is to implement our postmarket surveillance authority to maximize the likelihood that these postmarket plans will result in the collection of useful data. These data can reveal unforeseen adverse events, the actual rate of anticipated adverse events, and other information necessary to protect the public health.

§ 822.3 How do you define the terms used in this part?

Some of the terms we use in this part are specific to postmarket surveillance and reflect the language used in the statute (law). Other terms are more general and reflect FDA's interpretation of the law. This section of the part defines the following terms:

(a) *Act* means the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*), as amended.

(b) *Designated person* means the individual who conducts or supervises the conduct of your postmarket surveillance. If your postmarket surveillance plan includes a team of investigators, as defined below, the designated person is the responsible leader of that team.

(c) *Device failure* means a device does not perform or function as intended, and includes any deviation from the device's performance specifications or intended use.

(d) *General plan guidance* means agency guidance that provides information about the requirement to conduct postmarket surveillance, the submission of a plan to the agency for approval, the content of the submission, and the conduct and reporting requirements of the surveillance.

(e) *Investigator* means an individual who collects data or information in support of a postmarket surveillance plan.

(f) *Life-supporting or life-sustaining device used outside a device user facility* means that a device is essential to, or yields information essential to, the restoration or continuation of a bodily function important to the continuation of human life and is used outside a hospital, nursing home, ambulatory surgical facility, or diagnostic or outpatient treatment facility. A physician's office is not a device user facility.

(g) *Manufacturer* means any person, including any importer, repacker, and/or relabeler, who manufactures, prepares, propagates, compounds, assembles, processes, or engages in any of the activities described in § 807.3(d) of this chapter.

(h) *Postmarket surveillance* means the active, systematic, scientifically valid collection, analysis, and interpretation of data or other information about a marketed device.

(i) *Prospective surveillance* means that the subjects are identified at the beginning of the surveillance and data or other information will be collected from that time forward (as opposed to retrospective surveillance).

(j) *Serious adverse health consequences* means any significant adverse experience related to a device, including device-related events that are life-threatening or that involve permanent or long-term injuries or illnesses.

(k) *Specific guidance* means guidance that provides information regarding postmarket surveillance for specific types or categories of devices or specific postmarket surveillance issues. This type of guidance may be used to supplement general guidance and may address such topics as the type of surveillance approach that is appropriate for the device and the postmarket surveillance question, sample size, or specific reporting requirements.

(l) *Surveillance question* means the issue or issues to be addressed by the postmarket surveillance.

(m) *Unforeseen adverse event* means any serious adverse health consequence that is either not addressed in the labeling of the device or occurs at a rate higher than anticipated.

§ 822.4 Does this part apply to me?

If we have ordered you to conduct postmarket surveillance of a medical device under section 522 of the act, this part applies to you. We have the authority to order postmarket surveillance of any class II or class III medical device, including a device reviewed under the licensing provisions of section 351 of the Public Health Service Act, that meets any of the following criteria:

(a) Failure of the device would be reasonably likely to have serious adverse health consequences;

(b) The device is implanted in the human body for more than 1 year; or

(c) The device is used to support or sustain life and is used outside a user facility.

Subpart B—Notification

§ 822.5 How will I know if I must conduct postmarket surveillance?

We will send you a letter (the postmarket surveillance order) notifying you of the requirement to conduct postmarket surveillance. We may require that you submit information about your device that will allow us to better define the scope of a surveillance order. We will specify the device(s) subject to the surveillance order and the reason that we are requiring postmarket surveillance of the device under section 522 of the act. We will also provide you with any general or specific guidance that is available to help you develop your plan for conducting postmarket surveillance.

§ 822.6 When will you notify me that I am required to conduct postmarket surveillance?

We will notify you as soon as we have determined that postmarket surveillance of your device is necessary, based on the identification of a surveillance question. This may occur during the review of a marketing application for your device, as your device goes to market, or after your device has been marketed for a period of time.

§ 822.7 What should I do if I do not agree that postmarket surveillance is appropriate?

If you do not agree with our decision to order postmarket surveillance for a particular device, there are a number of mechanisms you may use to request review of our decision. These include:

(a) Requesting a meeting with the Director, Office of Surveillance and Biometrics, Center for Devices and Radiological Health, who generally issues the order for postmarket surveillance;

(b) Seeking internal review of the order under 21 CFR 10.75;

(c) Requesting an informal hearing under 21 CFR part 16; or

(d) Requesting review by the Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee.

Subpart C—Postmarket Surveillance Plan

§ 822.8 When, where, and how must I submit my postmarket surveillance plan?

You must submit your plan to conduct postmarket surveillance within 30 days of the date you receive the postmarket surveillance order. For devices regulated by the Center for Devices and Radiological Health, you should send three copies of your submission to the Center for Devices and Radiological Health, Postmarket Surveillance Document Center (HFZ–510), 1350 Piccard Dr., Rockville, MD, 20850. For devices regulated by the Center for Biologics Evaluation and Research, you should send three copies of your submission to Center for Biologics Evaluation and Research, Document Control Center, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. When we receive your original submission, we will send you an acknowledgement letter identifying the unique document number assigned to your submission. You should use this number in any correspondence related to this submission.

§ 822.9 What must I include in my submission?

Your submission must include the following:

(a) Organizational/administrative information:

(1) Your name and address;

(2) Generic and trade names of your device;

(3) Name and address of the contact person for the submission;

(4) Premarket application/submission numbers for your device;

(5) Table of contents identifying the page numbers for each section of the submission;

(6) Description of the device (this may be incorporated by reference to the appropriate premarket application/submission);

(7) Product codes and a list of all relevant model numbers; and

(8) Indications for use and claims for the device;

(b) Postmarket surveillance plan;

(c) Designated person information:

(1) Name, address, and telephone number; and

(2) Experience and qualifications.

§ 822.10 What must I include in my surveillance plan?

Your surveillance plan must include a discussion of:

(a) The plan objective(s) addressing the surveillance question(s) identified in our order;

(b) The subject of the study, e.g., patients, the device, animals;

(c) The variables and endpoints that will be used to answer the surveillance question, e.g., clinical parameters or outcomes;

(d) The surveillance approach or methodology to be used;

(e) Sample size and units of observation;

(f) Sources of data, e.g., hospital records;

(g) The data collection plan and forms;

(h) The patient followup plan, if applicable;

(i) The procedures for monitoring conduct and progress of the surveillance;

(j) An estimate of the duration of surveillance;

(k) All data analyses and statistical tests planned; and

(l) The content and timing of reports.

§ 822.11 What should I consider when designing my plan to conduct postmarket surveillance?

You must design your surveillance to address the postmarket surveillance question identified in the order you received. You should also consider the function, operating characteristics, and intended use of your device when designing a surveillance approach.

§ 822.12 Do you have any information that will help me prepare my submission or design my postmarket surveillance plan?

We have issued guidance for the development of postmarket surveillance plans which discusses the contents of a plan and points to consider in developing one. We have also issued guidance on criteria and approaches for postmarket surveillance, which discusses the criteria that we use to determine when postmarket surveillance under section 522 of the act is appropriate and necessary. The guidance identifies and discusses a broad range of surveillance approaches and describes the circumstances for which each would be suitable. These guidance documents are available on the Internet and from the Center for Devices and Radiological Health, Office of Surveillance and Biometrics (HFZ–510), 1350 Piccard Dr., Rockville, MD 20850.

§ 822.13 [Reserved]

§ 822.14 May I reference information previously submitted instead of submitting it again?

Yes, you may reference information that you have submitted in premarket submissions as well as other postmarket surveillance submissions. You must specify the information to be incorporated and the document number and pages where the information is located.

§ 822.15 How long must I conduct postmarket surveillance of my device?

The length of postmarket surveillance will depend on the postmarket surveillance question identified in our order. We may order prospective surveillance for a period up to 36 months; longer periods require your agreement. If we believe that a prospective period of greater than 36 months is necessary to address the surveillance question, and you do not agree, we will use our dispute resolution procedures.

Subpart D—FDA Review and Action

§ 822.16 What will you consider in the review of my submission?

First, we will determine that the submission is administratively complete. Then, in accordance with the law, we must determine whether the designated person has appropriate qualifications and experience to conduct the surveillance and whether the surveillance plan will result in the collection of useful data that will answer the surveillance question.

§ 822.17 How long will your review of my submission take?

We will review your submission within 60 days of receipt.

§ 822.18 How will I be notified of FDA's decision?

We will send you a letter notifying you of our decision and identifying any action you must take.

§ 822.19 What kinds of decisions may FDA make?

If your plan:	Then we will send you:	And you must:
(a) Should result in the collection of useful data that will address the postmarket surveillance question	An approval order, identifying any specific requirements related to your postmarket surveillance	Conduct postmarket surveillance of your device in accordance with the approved plan.
(b) Should result in the collection of useful data that will address the postmarket surveillance question after specific revisions are made or specific information is provided	An approvable letter identifying the specific revisions or information that must be submitted before your plan can be approved	Revise your postmarket surveillance submission to address the concerns in the approvable letter and submit it to us within the specified timeframe. We will determine the timeframe case by case, based on the types of revisions or information that you must submit.
(c) Does not meet the requirements specified in this part	A letter disapproving your plan and identifying the reasons for disapproval	Revise your postmarket surveillance submission and submit it to us within the specified timeframe. We will determine the timeframe case by case, based on the types of revisions or information that you must submit.
(d) Is not likely to result in the collection of useful data that will address the postmarket surveillance question	A letter disapproving your plan and identifying the reasons for disapproval	Revise your postmarket surveillance submission and submit it to us within the specified timeframe. We will determine the timeframe case by case, based on the types of revisions or information that you must submit.

§ 822.20 What are the consequences if I fail to submit a postmarket surveillance plan, my plan is disapproved and I fail to submit a new plan, or I fail to conduct surveillance in accordance with my approved plan?

The failure to have an approved postmarket surveillance plan or failure to conduct postmarket surveillance in accordance with the approved plan constitutes failure to comply with section 522 of the act. Your failure would be a prohibited act under section 301(q)(1)(B) of the act, and your device would be misbranded under section 502(t)(2) of the act. This means that we could seek to impose a number of penalties, including civil money penalties, criminal penalties, seizure of your products, or court injunction against further marketing of your device.

§ 822.21 What must I do if I want to make changes to my postmarket surveillance plan after you have approved it?

You must submit a request to make the proposed change and a revised postmarket surveillance plan (if needed) and receive our approval prior to making changes in your plan. You should identify this as a supplement to your postmarket surveillance submission, citing the unique document number that we assigned, and specifically identify the changes to the plan and the reasons/justification for making the changes in your cover letter.

§ 822.22 What recourse do I have if I do not agree with your decision?

If you disagree with us about the content of your plan or if we disapprove your plan, there are a number of mechanisms you may use to request review of our decision. These include:

(a) Requesting a meeting with the Director, Office of Surveillance and Biometrics, Center for Devices and Radiological Health, who generally issues the order for postmarket surveillance;

(b) Seeking internal review of the order under 21 CFR 10.75;

(c) Requesting an informal hearing under 21 CFR part 16; or

(d) Requesting review by the Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee.

§ 822.23 Is the information in my submission considered confidential?

We consider the content of your submission confidential until we have approved your postmarket surveillance plan. After we have approved your plan, the contents of the original submission and any amendments, supplements, or reports may be disclosed in accordance with the Freedom of Information Act. We will continue to protect trade secret and confidential commercial information after your plan is approved. We will not disclose information identifying individual patients. You may wish to indicate in your submission which information you consider trade secret or confidential commercial.

Subpart E—Responsibilities of Manufacturers

§ 822.24 What are my responsibilities when I am notified that I am required to conduct postmarket surveillance?

You must submit your plan to conduct postmarket surveillance to us within 30 days from receipt of the order (letter) notifying you that you are required to conduct postmarket surveillance of a device.

§ 822.25 What are my responsibilities after my postmarket surveillance plan has been approved?

After we have approved your plan, you must conduct the postmarket surveillance of your device in accordance with your approved plan. This means that you must ensure that:

(a) Postmarket surveillance is initiated in a timely manner;

(b) The surveillance is conducted in a scientifically sound manner and with due diligence;

(c) The data identified in the plan is collected;

(d) Any reports required as part of your approved plan are submitted to the agency in a timely manner; and

(e) Any information that we request prior to your submission of a report or in response to our review of a report is provided in a timely manner.

§ 822.26 If my company changes ownership, what must I do?

You must notify us within 30 days of any change in ownership of your company. Your notification should identify any changes to the name or address of the company, the contact person, or the designated person (as defined in § 822.3(b)). Your obligation to conduct postmarket surveillance will generally transfer to the new owner, unless you have both agreed that you will continue to conduct the surveillance. If you will continue to conduct the postmarket surveillance, you still must notify us of the change in ownership.

§ 822.27 If I go out of business, what must I do?

You must notify us within 30 days of the date of your decision to close your business. You should provide the expected date of closure and discuss your plans to complete or terminate postmarket surveillance of your device. You must also identify who will retain the records related to the surveillance (described in subpart G of this part) and where the records will be kept.

§ 822.28 If I stop marketing the device subject to postmarket surveillance, what must I do?

You must continue to conduct postmarket surveillance in accordance with your approved plan even if you no longer market the device. You may request that we allow you to terminate postmarket surveillance or modify your postmarket surveillance because you no longer market the device. We will make these decisions on a case-by-case basis, and you must continue to conduct the postmarket surveillance unless we notify you that you may stop your surveillance study.

Subpart F—Waivers and Exemptions

§ 822.29 May I request a waiver of a specific requirement of this part?

You may request that we waive any specific requirement of this part. You may submit your request, with supporting documentation, separately or as a part of your postmarket surveillance submission to the address in § 822.7.

§ 822.30 May I request exemption from the requirement to conduct postmarket surveillance?

You may request exemption from the requirement to conduct postmarket surveillance for your device or any specific model of that device at any time. You must comply with the requirements of this part unless and until we grant an exemption for your device. Your request for exemption must explain why you believe we should exempt the device or model from postmarket surveillance. You should demonstrate why the surveillance question does not apply to your device or does not need to be answered for the device for which you are requesting exemption. Alternatively, you may provide information that answers the surveillance question for your device with supporting documentation to the address in § 822.7.

Subpart G—Records and Reports

§ 822.31 What records am I required to keep?

You must keep copies of:

(a) All correspondence with your investigators or FDA, including required reports;

(b) Signed agreements from each of your investigators, when applicable, stating the commitment to conduct the surveillance in accordance with the

approved plan, any applicable FDA regulations, and any conditions of approval for your plan, such as reporting requirements;

(c) Your approved postmarket surveillance plan, with documentation of the date and reason for any deviation from the plan;

(d) All data collected and analyses conducted in support of your postmarket surveillance plan; and

(e) Any other records that we require to be maintained by regulation or by order.

§ 822.32 What records are the investigators in my surveillance plan required to keep?

Your investigator must keep copies of:

(a) All correspondence with another investigator, FDA, or you, including required reports.

(b) The approved postmarket surveillance plan, with documentation of the date and reason for any deviation from the plan.

(c) All data collected and analyses conducted for postmarket surveillance.

(d) Any other records that we require to be maintained by regulation or by order.

§ 822.33 How long must we keep these records?

You and your investigators must keep all records for a period of 2 years after we have accepted your final report, unless we specify otherwise.

§ 822.34 What must I do with the records if the sponsor of the plan or an investigator in the plan changes?

If the sponsor of the plan or an investigator in the plan changes, you must ensure that all records related to the postmarket surveillance have been transferred to the new sponsor or investigator and notify us within 10 days of the effective date of the change. You must provide the name, address, and telephone number of the new sponsor or investigator, certify that all records have been transferred, and provide the date of transfer.

§ 822.35 Can FDA inspect my manufacturing site or other sites involved in my postmarket surveillance plan?

We can review your postmarket surveillance programs during regularly scheduled inspections, inspections initiated to investigate recalls or other similar actions, and inspections initiated specifically to review your postmarket surveillance plan. We may also inspect any other person or site with postmarket surveillance obligations, such as clinical investigators or contractors. Any person authorized to grant access to a facility must permit authorized FDA employees to enter and inspect any facility where the device is held or where records regarding postmarket surveillance are held.

§ 822.36 Can FDA inspect and copy the records related to my postmarket surveillance plan?

We may, at a reasonable time and in a reasonable manner, inspect and copy any records pertaining to the conduct of postmarket surveillance that are required to be kept by this part. You must be able to produce records and information required by this part that are in the possession of others under contract with you to conduct the postmarket surveillance. We also expect those who have signed agreements or are under contract with you to produce the records and information upon our request. This information must be produced within 72 hours of the initiation of the inspection. We generally will redact information pertaining to individual subjects prior to copying those records, unless there are extenuating circumstances.

§ 822.37 Under what circumstances would FDA inspect records identifying subjects?

We can inspect and copy records identifying subjects under the same circumstances that we can inspect any records relating to postmarket surveillance. The agency is likely to be interested in such records if we have reason to believe that required reports have not been submitted, or are incomplete, inaccurate, false, or misleading.

§ 822.38 What reports must I submit to FDA?

You must submit interim and final reports as specified in your approved postmarket surveillance plan. In addition, we may ask you to submit additional information when we believe that the information is necessary for the protection of the public health and implementation of the act. We will also state the reason or purpose for the request and how we will use the information.

Dated: August 18, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–21827 Filed 8–28–00; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA 240–0254b; FRL–6856–5]

Revisions to the California State Implementation Plan, San Joaquin Valley Unified Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a revision to the San Joaquin Valley Unified Air Pollution Control District's (SJVUAPCD) portion of the California State Implementation Plan (SIP). This revision concerns volatile organic compound (VOC) emissions from the use of organic solvents. We are proposing to approve a local rule to regulate this emission source under the Clean Air Act as amended in 1990 (CAA or the Act).

DATES: Any comments on this proposal must arrive by September 28, 2000.

ADDRESSES: Mail comments to Andy Steckel, Rulemaking Office Chief (AIR–4), U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

You can inspect copies of the submitted SIP revision and EPA's technical support document (TSD) at our Region IX office during normal business hours. You may also see copies of the submitted SIP revision at the following locations:

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 2020 ''L'' Street, Sacramento, CA 95812.

San Joaquin Valley Unified Air Pollution Control District, 1999 Tuolumne Street, Suite #200, Fresno, CA 93721.

FOR FURTHER INFORMATION CONTACT: Yvonne Fong, Rulemaking Office (Air–4), U.S. Environmental Protection Agency, Region IX, (415) 744–1199.

SUPPLEMENTARY INFORMATION: This proposal addresses SJVUAPCD Rule 4661. In the Rules and Regulations section of this **Federal Register**, we are approving this local rule in a direct final action without prior proposal because we believe this SIP revision is not controversial. If we receive adverse comments, however, we will publish a timely withdrawal of the direct final rule and address the comments in a subsequent action based on this proposed rule. We do not plan to open a second comment period, so anyone interested in commenting should do so