Guidance for Industry and FDA Staff

SMDA to FDAMA: Guidance on FDA's Transition Plan for Existing Postmarket Surveillance Protocols

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U.S. Department Of Health And Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Postmarket Surveillance Studies Branch
Division of Postmarket Surveillance
Office of Surveillance and Biometrics

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to, Postmarket Surveillance Studies Branch, HFZ-543, 1350 Piccard Drive, Rockville, Maryland 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Laura A. Alonge at (301) 594-0639.

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Background:

The FDA Modernization Act of 1997 has significantly modified the statutory requirements for postmarket surveillance under section 522. Section 522 has been amended to remove the provision for Required Postmarket Surveillance (RPS) and has placed restrictions on the discretionary authority granted the agency. Under the new law, Postmarket Surveillance (PS) may be ordered only for those devices that are Class II or Class III the failure of which would be reasonably likely to have serious health consequences or which is intended to be (1) implanted in the human body for more than one year, or (2) [is] life sustaining or life supporting and used outside a device user facility.

Under the Safe Medical Devices Act (SMDA) of 1990 FDA had implemented RPS for 17 category "A" devices (permanent implants the failure of which could result in death or serious injury) and one category "C" device (plasma-sprayed porous coated hips). No postmarket surveillance orders have been issued for four of these devices (implantable cerebellar stimulator, implanted diaphragmatic/phrenic nerve stimulator, total artificial heart, and tracheal prosthesis) because there have been no "newly marketed" devices in these classifications since the implementation of RPS under SMDA. The Postmarket Surveillance Studies Branch (PSSB) has well over 100 original RPS submissions for the remaining 14 devices and must determine a mechanism for the transition of these existing submissions. In addition, the Discretionary Postmarket Surveillance (DPS) authority under SMDA has been used to order studies of a number of devices. FDA has undertaken to review each device area for which postmarket surveillance orders have been issued and determine whether postmarket surveillance under section 522 remains appropriate. The following factors were considered in the review:

- State of the technology - rapidly evolving, mature, clinical life, technology issues on the horizon, etc.
- Premarket path - PMA, supplement, 510(k), with or without clinical data
- Patient population exposed - demographics
- Public Health question (issue) to be addressed by PS - seriousness of failure, etc., endpoints
- Potential for PS to address the surveillance question - limitations (duration, indications for use, experience with current studies, etc.) imposed by the current protocols and/or the new statute
- Other potential postmarket strategies - postapproval studies, special controls, registries, etc.

- Recommendations for individual protocols (continue PS, terminate PS, etc.) already received and preliminary recommendations for imposition of PS under the new statute for new devices in these product areas.

Each device category may have some approved protocols, some protocols under review, and/or even some orders issued, but protocols not yet submitted. If the decision is to "terminate" postmarket surveillance, the orders would be rescinded or the studies closed out, as appropriate.

A decision to terminate postmarket surveillance, or to not use it in the future, does not mean that the Center is not concerned about a device category. It simply means that PS may not be the appropriate postmarket mechanism to address the Center's concerns.

The agency, by this guidance, is indicating that it expects to continue or discontinue postmarket surveillance (section 522) orders for the existing products as indicated on the following pages. Comments received on or before May 26, 1998, have been considered and incorporated into this document. Additional comments on this transition plan may be submitted at any time to Postmarket Surveillance Studies Branch, HFZ-543, 1350 Piccard Drive, Rockville, Maryland 20850.

Until a letter to terminate postmarket surveillance orders is issued and received by the sponsor, all existing orders will remain in effect.

This guidance document represents the agency's current thinking on the transition of existing postmarket surveillance protocols from requirements under SMDA to requirements under FDAMA. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be feasible if such approach satisfies the requirements of the applicable statute, regulations, or both.

FDA has determined that:

ANNULOPLASTY RING: The existing protocols were submitted for device modifications that in retrospect do not constitute significant changes. Postmarket surveillance orders for these two devices will be rescinded. In the future, PS may be ordered for a particular annuloplasty ring or rings if changes in design or materials raise specific public health concerns that cannot be addressed in the premarket arena.

All existing postmarket surveillance under section 522 will be terminated.

AUTOMATIC IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD): The ICD generator and lead system are constantly evolving. When an older model reaches the end of its useful life, it is replaced with a newer model with more features. Many of the early-generation ICD pulse generators are no longer marketed and do not remain implanted. Postmarket surveillance orders for ICD generators and lead systems will be rescinded because necessary information is contained in postapproval reports.

Existing postmarket surveillance under section 522 for ICD generators and lead systems will be terminated.

CARDIOVASCULAR PERMANENT PACEMAKER ELECTRODE (LEAD): Postmarket surveillance under existing orders will continue. Consider other surveillance strategies for new devices, technological changes, devices from new companies, and other evolutionary issues.

All existing postmarket surveillance under section 522 will continue.

CORONARY VASCULAR STENT: Postmarket surveillance for those stents that do not have 5-year postapproval study requirements will continue. Postmarket surveillance for stents that have postapproval (PMA) study requirements that duplicate or exceed the RPS requirements will be terminated.

Existing postmarket surveillance under section 522 for stents with postapproval (PMA) study requirements for a duration of 5 years or more will be terminated. Existing postmarket surveillance under section 522 for all other stents will continue.

IMPLANTABLE INFUSION PUMP: There is currently one RPS protocol for an infusion pump. This manufacturer was also ordered to conduct a postapproval (PMA) study and ODE and OSB worked with the manufacturer to develop a study design that would satisfy both requirements. It was agreed that OSB would be the lead Office for this particular study. This study will continue. However, ODE may impose postapproval (PMA) studies as appropriate for future devices.

All existing postmarket surveillance under section 522 will continue.

GLENOID FOSSA, MANDIBULAR CONDYLE, TEMPOROMANDIBULAR JOINT, AND INTERARTICULAR DISC (INTERPOSITIONAL IMPLANT) PROSTHESES: Postmarket surveillance of these devices will continue until after the 515(b) final notice. At that time postmarket performance should be monitored through postapproval studies required as a condition of PMA approval.

All existing postmarket surveillance under section 522 will continue.

IMPLANTABLE PULSE GENERATOR (PACEMAKER): Postmarket surveillance for pacemakers will be terminated because the pacemaker is a mature technology, its risks are well-characterized, and needed information is contained in postapproval reports.

All existing postmarket surveillance under section 522 will be terminated.

REPLACEMENT HEART VALVE: Required Postmarket Surveillance for heart valves will be terminated. The heart valve is a mature technology, its risks are well-characterized, and needed information is contained in postapproval reports. Discretionary Postmarket Surveillance of pyrolytic carbon valves, which was limited to in vitro fatigue testing, will be terminated. This in vitro data is now presented as part of the IDE or PMA application and no longer needs to be collected under the DPS authority.

All existing postmarket surveillance under section 522 will be terminated.

TOTAL ARTIFICIAL HEART: No orders issued; therefore, a transition plan is not applicable.

No existing postmarket surveillance under section 522.

VASCULAR GRAFT: Postmarket surveillance for current vascular grafts will be terminated because it is a low priority device, and is a mature technology. In the future, PS may be ordered for particular vascular grafts if changes in design or materials raise specific public health concerns that cannot be addressed in the premarket arena.

All existing postmarket surveillance under section 522 will be terminated.

VENTRICULAR BYPASS (ASSIST) DEVICE: Postmarket surveillance orders for two companies will be terminated. An RPS study completed by a third company demonstrated that the incidence of adverse events/complications has neither increased nor decreased since the device was marketed. Since these devices must have an approved PMA, the postapproval study is an appropriate mechanism for addressing any issues that remain unresolved at the time of PMA approval.

All existing postmarket surveillance under section 522 will be terminated.

TRACHEAL PROSTHESIS: No orders issued; therefore, a transition plan is not applicable.

No existing postmarket surveillance under section 522.

PLASMA SPRAYED POROUS COATED HIPS: Postmarket surveillance for some devices will be terminated, based on mechanical test data provided in the 510(k) submissions. Long-term RPS studies for those devices that have not demonstrated mechanical properties equivalent to those with sintered or diffusion-bonded porous coatings will continue.

Existing postmarket surveillance under section 522 for those hips with mechanical properties equivalent to sintered or diffusion-bonded porous coated hips will be terminated. Existing postmarket surveillance under section 522 for all other plasma sprayed porous coated hips will continue.

IMPLANTED CEREBELLAR STIMULATOR: No orders issued; therefore, a transition plan is not applicable.

No existing postmarket surveillance under section 522.

IMPLANTED DIAPHRAGMATIC/PHRENIC NERVE STIMULATOR: No orders issued; therefore, a transition plan is not applicable.

No existing postmarket surveillance under section 522.

INJECTABLE COLLAGEN: Discretionary Postmarket Surveillance for this product will be terminated. The information to be collected in the DPS study does not address substantial new questions from those answered by data contained within the PMA.

All existing postmarket surveillance under section 522 will be terminated.

SALINE BREAST IMPLANT: Discretionary Postmarket Surveillance of these devices will continue until after the 515(b) final notice. At that time postmarket performance should be monitored through postapproval studies required as a condition of PMA approval.

All existing postmarket surveillance under section 522 will continue.

HOME-USE PROTHROMBIN TIME TEST SYSTEM: Experience indicates that when clinical lab test systems move from professional use to lay (home) use it is a good idea to monitor the early experience. Problems with the device or the user's ability to interpret device output can occur. Some of the problems can cause serious injury or introduce new adverse events into what appeared to have been a safe and effective method of monitoring patients' condition. Postmarket surveillance of this product will continue.

All existing postmarket surveillance under section 522 will continue.

FDA DECISIONS

DEVICE CATEGORIES	TERMINATE EXISTING SURVEILLANCE ORDERS	TERMINATE SOME & CONTINUE SOME SURVEILLANCE ORDERS	TERMINATE SURVEILLANCE REQUIREMENTS - NO ORDERS ISSUED	CONTINUE EXISTING SURVEILLANCE ORDERS
Annuloplasty Ring	✓			
Automatic Implantable Cardioverter Defibrillator	✓			
Cardiovascular Permanent Pacemaker Electrode (lead)				✓
Coronary Vascular Stent		✓		
Glenoid Fossa Prosthesis				✓
Mandibular Condyle Prosthesis				✓
Total Temporomandibular Joint Prosthesis				✓
Interarticular Disc Prosthesis (interpositional implant)				✓
Implantable Infusion Pump				✓
Implantable Pacemaker Pulse Generator	✓			
Replacement Heart Valve	✓			
Total Artificial Heart			✓	
Vascular Graft Prosthesis (< 6 mm diameter)	✓			
Vascular Graft Prosthesis (≥ 6 mm diameter)	✓			
Ventricular Assist Device - Implant	✓			
Tracheal Prosthesis			✓	
Plasma Sprayed Porous Coated Hips		✓		
Implanted Cerebellar Stimulator			✓	
Implanted Diaphragmatic/phrenic Nerve Stimulator			✓	
Injectable Collagen	✓			
Saline Breast Implant				✓
Home-Use Prothrombin Time Test System				✓