of that program. The purpose of this collection is to obtain data upon which to base the computations for measuring State performance in meeting those goals and for allocating the bonus grant funds appropriated under the law.

Respondents: State, Local or Tribal Government.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
TANF quarterly Data Report, fy 1999 High Performance Bonus Awards	54	4	40	8,640
Emergency TAF Data Report	8	4	1218.5	6,992

Estimated Total Annual Burden Hours: 15,632.

Additional Information: Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW, Washington, DC 20503, Attn: Ms. Lori Schack.

Dated: May 24, 1999.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 99–13569 Filed 5–27–99; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97P–0354]

Orthopedic Devices; Reclassification of the Shoulder Joint Metal/Polymer/Metal Nonconstrained or Semi-Constrained Porous-Coated Uncemented Prosthesis

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of panel recommendation.

SUMMARY: The Food and Drug Administration (FDA) is announcing for public comment a recommendation of the Orthopedic and Rehabilitation Devices Panel (the Panel) to reclassify the shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis from class III into class II. The Panel made this recommendation after reviewing the reclassification petition submitted by the Orthopedic Surgical Manufacturers Association (OSMA) and other publicly available information. FDA is also announcing for public comment its tentative findings on the Panel's recommendations. After considering any public comments on the Panel's recommendations and FDA's tentative findings, FDA will approve or deny the reclassification petition by order in the form of a letter to the petitioner. FDA's decision on the reclassification petition will be announced in the **Federal Register**.

DATES: Written comments by August 26, 1999.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Theodore R. Stevens, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2036.

SUPPLEMENTARY INFORMATION:

I. Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the amendments) (Pub. L. 94–295), the Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101–629), and the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until the device is reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of the regulations.

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Reclassification of classified postamendments devices is governed by section 513(f)(2) of the act. This section provides that FDA may initiate the reclassification of a device classified into class III under section 513(f)(1) of the act, or the manufacturer or importer of a device may petition the Secretary of the Department of Health and Human

Services (the Secretary) for the issuance of an order classifying the device in class I or class II. FDA's regulations in § 860.134 (21 CFR 860.134) set forth the procedures for the filing and review of a petition for reclassification of such class III devices. In order to change the classification of the device, it is necessary that the proposed new class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

Under section 513(f)(2)(B)(i) of the act, the Secretary may, for good cause shown, refer a petition to a device classification panel. The Panel shall make a recommendation to the Secretary respecting approval or denial of the petition. Any such recommendation shall contain: (1) A summary of the reasons for the recommendation, (2) a summary of the data upon which the recommendation is based, and (3) an identification of the risks to health (if any) presented by the device with respect to which the petition was filed.

II. Regulatory History of the Device

The shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis intended to be implanted to replace the shoulder joint is a postamendment device classified into class III under section 513(f)(2) of the act. Therefore, the device cannot be placed in commercial distribution for implantation to replace the shoulder joint unless it is reclassified under section 513(f)(2), or subject to an approved premarket approval application (PMA) under section 515 of the act.

This action is taken in accordance with section 513(f)(2) of the act and § 860.134, based on information submitted in a petition for reclassification by OSMA received on July 23, 1997, requesting reclassification of the shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis from class III into class II (Ref. 1). Consistent with the act and the regulation, FDA referred the petition to the Panel for its recommendation on the requested changes in classification.

III. Device Description

The following device description is based on the Panel's recommendations and the agency's review.

A shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis is a device intended to be implanted to replace a shoulder joint. The device limits, with less than normal anatomic constraints, translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a humeral component made of alloys such as cobalt-chromium-molybdenum (Co-Cr-Mo) and/or titanium-aluminum-vanadium (Ti-6Al-4V) alloys, and a glenoid resurfacing component made of ultrahigh molecular weight polyethylene, or a combination of an articulating ultra-high molecular weight bearing surface fixed in a metal shell made of alloys such as Co-Cr-Mo and/or Ti-6Al-4V. The humeral component and glenoid backing have a substrate porous coating made of, in Co-Cr-Mo components, beads of the same alloy or commercially pure titanium powder, and in Ti-6Al-4V components, beads or fibers of commercially pure titanium or Ti-6Al-4V alloy, or commercially pure titanium powder. The porous coating has a volume porosity between 30 to 70 percent, an average pore size between 100 to 1,000 microns, interconnecting porosity, and a porous coating thickness of 600 to 1,500 microns. This generic type of device is designed to achieve biological fixation to bone without the use of bone cement.

IV. Recommendation of the Panel

At a public meeting on January 12 and 13, 1998, the Panel unanimously recommended that the shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis be reclassified from class III to class II. The Panel believed that class II with the proposed special controls (FDA Recognized Consensus Standards, Postmarket Surveillance, and FDA guidances) would reasonably ensure the safety and effectiveness of the device.

V. Risks to Health

After considering the information in the petition, the Panel's deliberations, the published literature, and the Medical Device Reports, FDA has evaluated the risks to health associated with the use of the shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis. FDA now believes that the following are risks to health associated with use of the device: Infection, adverse tissue reaction, pain and/or loss of function, and revision. FDA notes that these risks to health are also associated with the use of the cemented versions of shoulder joint prostheses.

A. Infection

Infection is a potential risk to health associated with all surgical procedures and implanted devices, and it occurs equally in patients implanted with cemented and uncemented shoulder joint prostheses (Ref. 1). The best defenses against infection are preventative measures, including selection of patients without known local and/or systematic infection, administration of perioperative antibiotics, implantation of a sterilized device, and strict adherence to sterile surgical technique.

B. Adverse Tissue Reaction

Adverse tissue reaction is a potential risk to health associated with all implanted devices (Ref. 1). If the materials used in the manufacture of shoulder prostheses are not biocompatible, the patient could have an adverse tissue reaction. The shoulder prosthesis identified in this notice are made of implant materials with an established, long history of safe use. In addition, the biocompatiblility of porous-coated implant materials has been shown to be comparable to those of the ''as cast'' materials.

C. Pain and/or Loss of Function

Pain and loss of shoulder function can occur with any shoulder arthroplasty. Some of the same kinds of device-related complications causing pain and loss of function are associated with implantation of both cemented and uncemented shoulder prostheses. These complications include: Early loosening due to inappropriate patient and/or device selection; inappropriate surgical technique and/or poor bone quality; some forms of metal and/or polyethylene wear which may cause osteolysis (dissolution of bone); and component disassembly, fracture, and/or failure. Dislocation and instability of the shoulder prosthesis may be due to either inappropriate surgical technique and/or component design or failure. However, other device-related complications resulting in pain and/or loss of function are directly or uniquely related to the porous coating(s) of uncemented shoulder prosthesis components. These complications include incomplete and/or slow biological ingrowth into the porous coating resulting in pain and dislocation/instability of the joint and delamination of the porous coating from the prosthesis components. Also, inadequate design and/or testing of the metal-backing of the glenoid component of uncemented shoulder prostheses may cause dislocation and instability which can result in pain and/or loss of function.

D. Revision

The incidence of revision for uncemented shoulder prostheses is comparable to the revision rates of cemented total shoulder arthroplasty (Ref. 1). The major causes for revision of uncemented shoulder prostheses are failure of the metal-backed glenoid component or incomplete humeral fixation.

VI. Summary of the Reasons for the Recommendations

After considering the data and information contained in the petition and provided by FDA, the open discussions during the Panel meeting, and their personal knowledge of and clinical experience with the device, the Panel gave the following reasons in support of its recommendations to reclassify the generic device, the shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis intended to replace a shoulder joint from class III into class II. The Panel believes that the device should be reclassified into class II because special controls, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the device, and there is sufficient information to establish special controls to provide such assurance.

VII. Summary of Data Upon Which the Panel Recommendation Is Based

In addition to the potential risks to health of the shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis described in section V of this document, there is reasonable knowledge of the benefits of the device. Both cemented and uncemented shoulder prostheses provide decreased pain or cessation of pain and increased mobility and function, post-operatively resulting in an overall improved quality of patient life. A specific benefit of the uncemented shoulder prosthesis is the absence of risks associated with the use of bone cement (e.g., embolism and bone cement breakdown) and easier revision if revision should become indicated due to loosening.

VIII. Special Controls

FDA believes that the special controls identified below in this document, in addition to general controls, are adequate to control the identified risks to health for this device. FDA agrees with the Panel that consensus standards and the FDA guidances are appropriate special controls to reasonably ensure the safety and effectiveness of the device. However, FDA disagrees with the Panel that postmarket surveillance is a necessary or appropriate special control for this device.

In their deliberations, the Panel stated that it was important that adverse device outcomes should be reported to FDA. The Panel thought that adverse device outcomes should be tracked through postmarket surveillance. FDA agrees with the Panel that adverse device outcomes should be reported to FDA. However, FDA believes that another postmarket mechanism better addresses the Panel's concern that adverse device outcomes should be reported to FDA. FDA believes that the existing mandatory Medical Device Reporting system is the appropriate mechanism to report such adverse events. Therefore, postmarket surveillance is unnecessary to address the Panel's concerns, and to reasonably ensure the safety and effectiveness of the device.

Based on the available information, FDA identified these 10 voluntary standards from the American Society for Testing and Materials (ASTM) and 5 FDA guidance documents as the specific special controls to reasonably ensure the safety and effectiveness of the shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis as follows:

A. ASTM Standards:

1. ASTM F 67–95, ''Standard Specifications for Unalloyed Titanium for Surgical Implant Applications;''

2. ASTM F 75–92, ''Standard Specification for Cast Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implant Applications;''

3. ASTM F 136–96, ''Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial Alloy (R56401)) for Surgical Implant Applications;''

4. ASTM F 648–98, ''Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants;''

5. ASTM F 1044–95, ''Standard Test Method for Shear Testing of Porous Metal Coatings;''

6. ASTM F 1147–95, ''Standard Test Method for Tension Testing of Porous Metal Coatings;''

7. ASTM F 1160–91, ''Standard Test Method for Constant Stress Amplitude Fatigue Testing of Porous Metal-Coated Metallic Materials;''

8. ASTM F 1377–92, ''Standard Specification for Cobalt-28 Chromium-6 Molybdenum Powder for Coating of Orthopedic Implants;''

9. ASTM F 1378–97, ''Standard Specification for Shoulder Prostheses;'' and

10. ASTM F 1580–95, ''Standard Specification for Titanium and Titanium-6% Aluminum-4% Vanadium Alloy Powders for Coatings of Surgical Implants.''

The ASTM standards define implant material specifications and testing methods applicable to the shoulder joint metal/polymer/metal nonconstrained or unconstrained uncemented prosthesis. Adherence to these standards and comparison of the results from these standard test methods can control the risks to health of adverse tissue reaction, pain and/or loss of function, and revision by having the manufacturer use surgical implant quality materials and assuring that the device has acceptable performance through mechanical testing.

Nine of the ASTM standards are FDA recognized consensus standards. FDA is now reviewing ASTM F1378–97, ''Standard Specification for Shoulder Prostheses'' for inclusion in the list of FDA recognized consensus standards. By the time this proposal is finalized as a final rule, ASTM F1378 is expected to be an FDA recognized consensus standard.

ASTM standards may be obtained from ASTM Customer Services, 100 Barr Harbor Dr., West Conshohocken, PA 19428 (Telephone 610–832–9585). ASTM has a site on the world wide web at ''http://www.astm.org/''.

B. FDA Guidances:

1. ''Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement'' (Facts-on-Demand # 827);

2. ''Guidance Document for Testing Non-articulating, 'Mechanically Locked' Modular Implant Components'' (Facts-on-Demand # 916);

3. ''Draft Guidance Document for the Preparation of Premarket Notification (510(k)) Applications for Orthopedic Devices-The Basic Elements'' (Facts-on-Demand # 832);

4. ''Use of International Standard ISO–10993, Biological Evaluation of Medical Devices Part I: Evaluation and Testing'' (Facts-on-Demand # 164) ; and

5. ''510(k) Sterility Review Guidance—and Revision of 11/18/94 #K90–1'' (Facts-on-Demand # 361).

FDA guidance documents provide guidance on how to meet general orthopedic device premarket notification (510(k)) requirements, including biocompatibility testing, sterility testing, mechanical performance testing, and physician and

patient labeling for the shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis. Use of the preclinical section of the FDA guidance documents can control the risks to health of adverse tissue reaction, infection, pain and/or loss of function, and revision by having manufacturers use surgical quality implant materials, adequately test and sterilize their devices, and provide adequate directions for use (and patient information).

To receive a guidance via fax machine, telephone Center for Devices and Radiological Health's (CDRH) CDRH Facts-on-Demand system at 800–399–0381, or 301–827–0111 from a touch-tone telephone. At the first voice prompt, press 1 to access the Division of Small Manufacturers Assistance Fax, at the second voice prompt, press 2, and then enter the document number followed by the pound sign (#). Then follow the remaining voice prompts to complete your request. The guidances are also available from the CDRH world wide web address at ''http://www.fda.gov/cdrh''.

IX. FDA's Tentative Findings

FDA believes that the shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis should be reclassified into class II because special controls, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the device, and there is sufficient information to establish special controls to provide such assurance.

X. References

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

1. Petition for Reclassification of Orthopaedic Shoulder Prostheses submitted by the Orthopedic Surgical Manufacturers Association, Warsaw, IN, received July 23, 1997.

2. Transcript of the Orthopedic and Rehabilitation Devices Panel Meeting, January 12 and 13, 1998, vol. I, pp. 12 to 114.

XI. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this reclassification action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

XII. Analysis of Impacts

FDA has examined the impacts of the notice under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Pub. L. 104–121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4)). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety and other advantages, distributive impacts and equity). The agency believes that this reclassification action is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the reclassification action is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Reclassification of the device from class III to class II will relieve manufacturers of the cost of complying with the premarket approval requirements in section 515 of the act. Because reclassification will reduce regulatory costs with respect to this device, it will impose no significant economic impact on any small entities, and it may permit small potential competitors to enter the marketplace by lowering their costs. The agency therefore certifies that this reclassification action, if finalized, will not have a significant economic impact on a substantial number of small entities. In addition, this reclassification action will not impose costs of $100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

XIII. Request for Comments

Interested persons may, on or before (*insert date 90 days after date of publication in the* **Federal Register**), submit to the Dockets Management Branch (address above) written comments regarding this document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m. Monday through Friday.

Dated: May 17, 1999.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 99–13470 Filed 5–27–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 98E–0485 and 98E–0850]

Determination of Regulatory Review Period for Purposes of Patent Extension; Therma Choice™ Uterine Ballon Therapy System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Therma Choice™ Uterine Ballon Therapy System and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that medical device.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6620.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices,