type design that are certificated for operation in the United States.

Proposed Requirements of This AD

Since an unsafe condition has been identified that is likely to exist or develop on other Turbomeca S.A. Arriel–1D, –1D1, –1S, –1S1, –2S1 and –2B series turboshaft engines of the same type design that are used on rotocraft registered in the United States, the proposed AD would require insertion of a sleeve in the attachment boss of the compresser bleed valve. The actions would be required to be accomplished in accordance with the SB's described previously.

Economic Impact

There are approximately 1,406 engines of the affected design in the worldwide fleet. The FAA estimates that 476 engines installed on aircraft of U.S. registry would be affected by this proposed AD. The FAA also estimates that it would take approximately 0.5 work hours per engine to accomplish the proposed actions, and that the average labor rate is $60 per work hour. Required parts would cost approximately $430 per engine. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $218,960.

Regulatory Impact

This proposed rule does not have federalism implications, as defined in Executive Order 13132, because it would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the FAA has not consulted with state authorities prior to publication of this proposed rule.

For the reasons discussed above, I certify that this proposed regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Turbomeca S.A.: Docket No. 2001–NE–06–AD.

Applicability

This airworthiness directive (AD) is applicable to Turbomeca S.A. Arriel–1D, –1D1, –1S, –1S1, –2S1 and –2B series turboshaft engines. These engines are installed on, but not limited to, Eurocopter France AS350B1, AS350B2, AS350B3; Astar 350D, Fennic AD550U2 and Sikorsky S–76A and S–76C series helicopters.

Note 1: This AD applies to each engine identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For engines that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance

Compliance with this AD is required within 30 days after the effective date of this AD, unless already done. To prevent acoustic excitation of the centrifugal compressor impeller blades resulting in contained blade ruptures and power loss that could lead to an uncommanded in-flight shutdown, do the following:

(a) Remove the compressor bleed valve, install the sleeve at the bottom of the boss attachment and install the valve as follows:

(1) For Arriel 2S1 and –2B engines in accordance with Paragraph 2.B. and 2.C. of Turbomeca S.A. Service Bulletin (SB) No. 292 72 2054, dated September 20, 1999.

(2) For Arriel 1D, –1D1, –1S, and –1S1 engines in accordance with Paragraph 2.B. and 2.C. of Turbomeca S.A. SB No. 292 72 0261, dated September 20, 1999.

Alternative Methods of Compliance

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Engine Certification Office (ECO). Operators shall submit their request through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, ECO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the ECO.

Special Flight Permits

(c) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the helicopter to a location where the requirements of this AD can be accomplished.

Note 3: The subject of this AD is addressed in Direction Generale de L'Aviation Civile (DGAC) Airworthiness Directives No. 1999–391(A) and 1999–392 (A), dated October 6, 1999.

Issued in Burlington, Massachusetts, on August 28, 2001.

Jay J. Pardee,

Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 01–22313 Filed 9–5–01; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. 99P–1864]

Orthopedic and Rehabilitation Devices: Reclassification of the Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify the hip joint metal/polymer constrained cemented or uncemented prosthesis intended to replace a hip joint from class III (premarket approval) to class II (special controls). The agency is also proposing to revise the device identification. This reclassification is based upon new information regarding the device contained in a reclassification petition submitted by the Orthopedic Surgical Manufacturers Association. The agency is also publishing the recommendation of the Orthopedic and Rehabilitation Devices Panel (the Panel) regarding the

classification of this device. After considering public comments on the proposed classification, FDA will publish a final regulation classifying this device. This action is being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990 (SMDA), and the Food and Drug Administration Modernization Act of 1997 (FDAMA). Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of a draft guidance document that would serve as the special control if this proposal becomes final.

DATES: Submit written or electronic comments by December 5, 2001. See section XIII of this document for the proposed effective date of a final rule based on this document.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061 Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

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

SUPPLEMENTARY INFORMATION:

I. Background (Regulatory Authorities)

The act (21 U.S.C. 301 *et seq.*), as amended by the 1976 amendments (Public Law 94–295), the SMDA (Public Law 101–629), and FDAMA (Public Law 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: (1) The device is reclassified into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with new section 513(f)(2) of the act, as amended by FDAMA; or (3) FDA issues an order finding the device to be substantially equivalent, in accordance with 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 part 807 of the regulations (21 CFR part 807).

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 preamendments devices is governed by section 513(e) of the act. This section provides that FDA may, by rulemaking, reclassify a device (in a proceeding that parallels the initial classification proceeding) based upon ''new information.'' The reclassification can be initiated by FDA or by the petition of an interested person. The term ''new information,'' as used in section 513(e) of the act, includes information developed as a result of a reevaluation of the data before the agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, e.g., *Holland Rantos* v. *United States Department of Health, Education, and Welfare,* 587 F.2d at 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn* v. *Finch*, 422 F.2d 944 (6th Cir. 1970); *Bell* v. *Goddard*, 366 F.2 177 (7th Cir. 1966).

Reevaluation of the data previously before the agency is an appropriate basis for subsequent regulatory action where the reevaluation is made in light of newly available regulatory authority (See *Bell* v. *Goddard*, supra, 366 F.2d at 181; *Ethicon, Inc.* v. *FDA*, 762 F. Supp. 382, 389–91 (D.D.C. 1991)), or in light of changes in ''medical science.'' (See *Upjohn* v. *Finch*, supra, 422 F.2d at 951.) Regardless of whether data before the agency are past or new data, the ''new information'' upon which reclassification under section 513(e) of the act is based must consist of ''valid scientific evidence,'' as defined in section 513(a)(3) and 21 CFR 860.7(c)(2). (See, e.g., *General Medical Co.* v. *FDA*, 770 F.2d 214 (D.C. Cir 1985); *Contact Lens Assoc.* v. *FDA*, 766 F.2d 592 (D.C.Cir.), cert. denied, 474 U.S. 1062 (1985)). FDA relies upon ''valid scientific evidence'' in the classification process to determine the level of regulation for devices. For the purpose of reclassification, the valid scientific evidence upon which the agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., the contents of a pending PMA. (See section 520(c) of the act (21 U.S.C. 360j(c).)

II. Regulatory History of the Device

In the **Federal Register** of September 4, 1987 (52 FR 33686), FDA issued a final rule classifying the hip joint metal/polymer constrained cemented or uncemented prosthesis into class III (21 CFR 888.3310). The preamble to the proposal to classify the device (47 FR 29052, July 2, 1982) included the recommendation of the Orthopedic Device Section of the Surgical and Rehabilitation Devices Panel (the Orthopedic Section of the Panel or the Panel), a FDA advisory committee that met regarding the classification of the device. The Orthopedic Section of the Panel recommended that the device be classified into class III because the device is implanted and intended to relieve disabling pain and to restore or minimize further loss of functional use of the hip joint or limb.

The Orthopedic Section of the Panel identified the following three risks to health associated with use of the device: (1) Loss or reduction of joint function, (2) adverse tissue reaction, and (3) infection. Improper design or inadequate mechanical properties of the device, such as a lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, device deformation, or loosening of the device. Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away of material from the surface of the device and the subsequent release of material into the surrounding tissues and systemic circulation. The

implantation of the device may also lead to an increased risk of infection.

FDA agreed with the classification recommendation of the Orthopedic Section of the Panel. The preamble to the final rule classifying the device into class III advised that the earliest date by which PMA's for the device could be required was March 30, 1990, or 90 days after issuance of a rule requiring premarket approval for the device, whichever occurred later.

In the **Federal Register** of May 6, 1994 (59 FR 23731), FDA categorized the hip joint metal/polymer constrained cemented or uncemented prosthesis as a group 1 device that FDA believed had fallen into disuse or limited use. FDA believed that rulemaking under section 515(b) of the act was unlikely to result in viable PMAs or reclassification petitions for the device. In the **Federal Register** of September 7, 1995 (60 FR 46718), FDA published a proposed rule to require the filing of a PMA or notice of completion of a product development protocol (PDP) for 43 preamendments class III medical devices, including the hip joint metal/polymer constrained cemented or uncemented prosthesis. The agency received no comments regarding the proposed rule for the device. In the **Federal Register** of September 27, 1996 (61 FR 50704), FDA published a final rule requiring PMAs or PDPs for 41 of the class III devices, including the hip joint metal/polymer constrained cemented or uncemented prosthesis by December 26, 1996.

In December 1996, FDA received two PMAs for the device. On December 13, 1996, Howmedica Osteonics Corp. submitted a PMA for the Osteonics Constrained Hip Acetabular Insert. On December 26, 1996, Depuy, Orthopaedics, Inc. (Depuy), submitted a PMA for the S-Rom Poly-Dial Constrained Liner. Consistent with the act and the regulations, FDA consulted with the Panel regarding the approvability of the two PMAs. At a public meeting on June 10, 1997, the Panel unanimously recommended both PMAs for approval with conditions. In its deliberations on both PMAs, the Panel noted the long use of the device and the acceptable rate of complications associated with its use. FDA agreed with the Panel's recommendations and approved the Howmedica Osteonics Corp. Osteonics Constrained Hip Acetabular Insert on June 13, 1997, and the Depuy S-Rom Poly-Dial Constrained Liner on June 19, 1997.

On June 9, 1999, the agency filed a reclassification petition for the hip joint metal/polymer constrained cemented or uncemented prosthesis from OSMA that was dated June 1, 1999, and amended on June 8 and August 27, 1999. The petition requested that the device be reclassified from class III into class II. The petition included new information that was not available in 1996 when the final rule requiring PMAs or PDPs for the device was issued. Consistent with the act and the regulations, FDA consulted with the Panel regarding the possible reclassification of this device.

III. Device Description

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

A hip joint metal/polymer constrained cemented or uncemented prosthesis is a device intended to be implanted to replace a hip joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and an acetabular component made of ultra-high-molecular-weight polyethylene with or without a metal shell made of alloys, such as cobalt-chromium-molybdenum and titanium alloys. This generic type of device is intended for use with or without bone cement (21 CFR 888.3027).

This revised identification more accurately describes the currently marketed hip joint metal/polymer constrained cemented or uncemented prosthesis.

IV. Recommendation of the Panel

At a public meeting on November 4, 1999, the Panel recommended that the hip joint metal/polymer constrained cemented or uncemented prosthesis intended to replace a hip joint be reclassified from class III into class II (Ref. 2). The Panel believed that class II with special controls would provide reasonable assurance of 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 hip joint metal/polymer constrained cemented or 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 other hip joint prostheses. In section VIII of this document, FDA describes a class II special controls guidance that addresses these risks to health.

A. Infection

Infection is a potential risk to health associated with all surgical procedures and implanted devices, and it occurs in patients implanted with metal/polymer constrained hip joint prostheses (Ref. 1). The best defenses against infection are preventive measures, including selection of patients without known local and/or systemic 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 metal/polymer constrained hip joint prostheses are not biocompatible or adequately wear resistant, the patient could have an adverse tissue reaction.

C. Pain and/or Loss of Function

Pain and loss of hip joint function can occur with any hip arthroplasty. Loosening due to inappropriate patient and/or device selection; inappropriate surgical technique and/or poor bone quality; metal and/or polyethylene wear that may cause osteolysis (dissolution of bone); dislocation and instability due to inappropriate surgical technique and/or component design or failure; and component disassembly (e.g., disengagement of the metal reinforcing ring from the outer rim of the acetabular cup), fracture, and/or failure are potential complications that may result in pain and/or loss of hip joint function. In addition, because the constrained total hip prosthesis has components that are linked together across the joint, there is typically a reduction in the range of hip joint motion compared to a semi-constrained total hip prosthesis.

D. Revision

Revision is a potential risk to health associated with any hip arthroplasty. The major causes for revision of the metal/polymer constrained hip joint prosthesis are infection, adverse tissue reaction, and pain and/or loss of function. Revision hip arthroplasty typically has a lower clinical success rate than primary hip arthroplasty.

VI. Summary of Reasons for Recommendation

After considering the information in the petition and provided by FDA, the discussion during the Panel meeting,

and their personal knowledge of and clinical experience with the device, the Panel gave two reasons in support of its recommendation to classify the generic type hip joint metal/polymer constrained cemented or uncemented prosthesis intended to replace a hip joint from class III into class II. The Panel believed the device should be classified 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 the Data Upon Which the Recommendation is Based

In addition to the potential risks to health of the hip joint metal/polymer constrained cemented or uncemented prosthesis described in section V of this document, there is reasonable knowledge of the benefits of the device (Ref.1). The device provides decreased pain or cessation of pain and increased mobility and function, resulting in an overall improved quality of patient life. In addition, the device may help to reduce the recurrence of dislocation. Based on the available information, FDA believes the special control discussed in section VIII of this document is capable of providing reasonable assurance of the safety and effectiveness of the device with regard to the identified risks to health of the device.

VIII. Special Controls

FDA believes that, in addition to general controls, the class II special controls guidance document entitled ''Class II Special Controls Guidance: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis'' (the class II special controls guidance) is an adequate special control to address the risks to health described in section V of this document. The class II special controls guidance provides information on how to meet premarket notification (510(k)) submission requirements for the device, including a list of relevant FDA orthopedic device guidance documents, voluntary consensus standards from the American Society for Testing and Materials and International Organization for Standardization, and labeling statements. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of this guidance document that FDA intends to use as the special control for this device.

The FDA guidance documents identified in the class II special controls guidance provide information on how to meet general orthopedic device premarket notification (510(k)) requirements, including biocompatibility testing, sterility testing, mechanical performance testing, and labeling. The FDA guidance documents can help control the risks to health of infection, adverse tissue reaction, pain and/or loss of function, and revision by having manufacturers address the need to use surgical quality implant materials, adequately test and sterilize their devices, and provide adequate instructions for use.

The voluntary consensus standards identified in the class II special controls guidance for the device define implant material specifications, testing methods, and performance criteria applicable to the hip joint metal/polymer constrained cemented or uncemented prosthesis. Adherence to these standards and comparison of the results from these test methods can control the risks of adverse tissue reaction, pain and/or loss of function, and revision by having manufacturers use surgical quality implant materials, adequately test their devices, and assure that the device has acceptable mechanical performance.

The labeling information listed in the class II special controls guidance identifies the intended use, specific indications for use, and precautions for use of the device. Adequate instructions for use by manufacturers can control the risks to health of adverse tissue reaction, pain and/or loss of function, and revision.

IX. FDA's Tentative Findings

FDA believes that the hip joint metal/polymer constrained cemented or uncemented prosthesis intended to replace a hip joint should be classified 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. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this proposed classification 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.

XI. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4)). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the proposed rule 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. Because the proposed rule classifying this device into class II will relieve all manufacturers of the device from the cost of complying with the premarket approval requirements in section 515 of the act, it will impose no significant economic impact on any small entities. The agency therefore certifies that this proposed rule, if finalized, will not have a significant economic impact on a substantial number of small entities. In addition, this proposed rule 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 or analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

XII. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no information that is subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995. The proposed special control does not require the respondent to submit additional information.

XIII. Submission of Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this proposal by December 5, 2001. 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. FDA proposes that any final regulation

that may issue based on this proposal become effective 30 days after its publication in the **Federal Register**.

XIV. 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 the reclassification of hip joint metal/polymer constrained cemented or uncemented prosthesis submitted by the Orthopedic Surgical Manufacturers Association, Warsaw, IN, dated June 1, 1999, amended June 8 and August 27, 1999.

2. Transcript of the Orthopedic and Rehabilitation Devices Panel Meeting, November 4, 1999, pp. 25 to 142.

List of Subjects in 21 CFR Part 888

Medical devices.

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 888 be amended as follows:

PART 888—ORTHOPEDIC DEVICES

1. The authority citation for 21 CFR part 888 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 888.3310 is revised to read as follows:

§ 888.3310 Hip joint metal/polymer constrained cemented or uncemented prosthesis.

(a) *Identification*. A hip joint metal/polymer constrained cemented or uncemented prosthesis is a device intended to be implanted to replace a hip joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and an acetabular component made of ultra-high-molecular-weight polyethylene with or without a metal shell, made of alloys, such as cobalt-chromium-molybdenum and titanium alloys. This generic type of device is intended for use with or without bone cement (§ 888.3027).

(b) *Classification*. Class II (special controls). This special control for this device is the FDA guidance document entitled ''Class II Special Controls Guidance Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis.''

Dated: August 22, 2001.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 01–22286 Filed 9–5–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300, 1301, 1304, 1305 and 1306

[DEA–208P]

RIN 1117–AA58

Allowing Central Fill Pharmacies To Fill Prescriptions for Controlled Substances on Behalf of Retail Pharmacies

AGENCY: Drug Enforcement Administration (DEA), Justice

ACTION: Notice of proposed rulemaking

SUMMARY: DEA is proposing to amend its regulations to provide for the use of central fill pharmacies, also known as refill pharmacies, fulfillment centers, or call centers. Unlike retail pharmacies which dispense controlled substances directly to the patient, central fill pharmacies provide a service to retail pharmacies by preparing and packaging prescriptions for retail pharmacies to dispense to the patient. Prescription information is transmitted from a retail pharmacy to a central fill pharmacy where the prescription is filled or refilled. The filled prescription is delivered to the retail pharmacy for pick up by the patient. Industry has expressed interest in utilizing central fill pharmacy operations to allow for more efficient delivery of prescriptions to patients. With this rulemaking, DEA is proposing to expand the definition of ''dispense'' to include the activities of central fill pharmacies. Mail order and Internet pharmacies, which currently obtain prescriptions from and dispense directly to a patient, are not affected by this regulation. They will continue to be registered as retail pharmacies.

DATES: Written comments must be submitted on or before November 5, 2001.

ADDRESSES: Comments should be submitted in triplicate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA **Federal Register** Representative/CCR.

FOR FURTHER INFORMATION CONTACT: Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537. Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION:

What Is the Purpose of the Proposed Rule?

DEA is proposing these amendments in response to significant changes taking place in the pharmacy industry. Increased demands are being placed on traditional pharmacy systems by the rapid growth in the number of prescriptions written and dispensed. The National Association of Chain Drugstores recently estimated that in 2005, pharmacists in the United States will fill over 4 billion prescriptions. While the number of prescriptions dispensed is growing dramatically, the United States is facing a severe pharmacist shortage. Between 1999–2004, the volume of prescriptions dispensed in retail pharmacies is expected to increase 35%, while during the same period the number of available pharmacists is projected to increase only 6%. These factors have forced the pharmacy industry to seek new ways to increase efficiency while maintaining quality patient care. By transferring some of the time-consuming, non-clinical duties such as prescription filling to central fill pharmacies, traditional retail pharmacies can dedicate more time to assisting patients.

In response to industry's interest in improving efficiency by implementing the concept of central fill pharmacies, DEA contacted a variety of relevant trade associations and professional organizations to obtain more information on the issue. Several segments of the industry submitted written comments to DEA's solicitation; two others, including one trade association and one company, requested to meet with DEA to provide additional information. After considering the issues raised by industry, DEA determined that changes to the regulations would be appropriate and would give industry needed flexibility to accommodate the tremendous growth in the number of prescriptions presented for dispensing.

DEA's current regulations do not permit the utilization of central fill pharmacies for the dispensing of controlled substances. With this rulemaking, DEA is proposing several amendments to its regulations to allow for the use of central fill pharmacies, subject to certain restrictions, in states where such activities are permitted. While DEA is committed to responding to emerging industry practices, such as central fill pharmacies, which will