protect the confidentiality of the data and to prevent unauthorized access to the data.

In addition, CMS has physical safeguards in place to reduce the exposure of computer equipment and thus achieve an optimum level of protection and security for the CMS system. For computerized records, safeguards have been established in accordance with HHS standards and National Institute of Standards and Technology guidelines; *e.g.*, security codes will be used, limiting access to authorized personnel. System securities are established in accordance with HHS, Information Resource Management Circular #10, Automated Information Systems Security Program; CMS Information Systems Security, Standards Guidelines Handbook and OMB Circular No. A–130 (revised) Appendix III.

RETENTION AND DISPOSAL:

The records are maintained on-line in the system for 2 years. After a 2-year period, records are transferred to an archive file and destroyed three years later.

Due to a freeze imposed by the Department of Justice in 1992, correspondence documenting/supporting a specific claim, reconsideration, appeal or similar case will be maintained until further notice. Once the freeze is lifted, destroy 6 years and 3 months after final payment/resolution.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Division of Correspondence Control, Office of Communications and Operations Support, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

NOTIFICATION PROCEDURE:

For purpose of access, the subject individual should write to the system manager, who will require the system name, the subject individual's name (woman's maiden name, if applicable), social security number (SSN) (furnishing the SSN is voluntary, but it may make searching for a record easier and prevent delay), address, date of correspondence.

RECORD ACCESS PROCEDURES:

For purpose of access, use the same procedures outlined in Notification Procedures above. Requestors should also reasonably specify the record contents being sought. (These procedures are in accordance with Department regulation 45 CFR 5b.5(a)(2).)

CONTESTING RECORD PROCEDURES:

The subject individual should contact the system manager named above, and reasonably identify the record and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These procedures are in accordance with Department regulation 45 CFR 5b.7.)

RECORD SOURCE CATEGORIES:

Incoming correspondence and responses to such correspondence.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 02–22742 Filed 9–5–02; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01P–0343]

Orthopedic Devices; Denial of Request for Change in Classification of Hip Joint Metal/Metal Semi-Constrained, With a Cemented Acetabular Component, Prosthesis and Hip Joint Metal/Metal Semi-Constrained, With an Uncemented Acetabular Component, Prosthesis

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; denial of petition.

SUMMARY: The Food and Drug Administration (FDA) is denying the petition submitted by the Orthopedic Surgical Manufacturers Association (OSMA) to reclassify the hip joint metal/metal semi-constrained prosthesis with a cemented acetabular component and the hip joint metal/metal semi-constrained prosthesis with an uncemented acetabular component from class III (premarket approval) into class II (special controls). The agency is denying the petition because OSMA failed to provide any new information to establish that special controls would provide reasonable assurance of the safety and effectiveness of the devices. The agency is also publishing the recommendation of FDA's Orthopedic and Rehabilitation Devices Panel (the Panel) concerning the petition. 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).

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

SUPPLEMENTARY INFORMATION:

I. Classification and Reclassification of Devices Under the Amendments

The act (21 U.S.C. 301 *et seq.*), as amended by the 1976 amendments (Public Law 94–295), 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). Except as provided in section 520(c) of the act (21 U.S.C. 360j(c)), FDA may not use confidential information concerning a device's safety and effectiveness as a basis for reclassification of the device from class III into class II or class I.

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 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 preamendment 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, 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 marketed 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.

Reclassification of classified preamendments devices is governed by section 513(e) of the act. This section of the act provides that FDA may, by rulemaking, reclassify a device (in a proceeding that parallels the initial classification proceeding) based on ''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) and 515(b)(2)(A)(iv) of the act (21 U.S.C. 360e(b)(2)(A)(iv)), 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 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn v. Finch*, 422 F.2d 944 (6th Cir. 1970); *Bell v. Goddard*, 366 F.2d 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) of the act and § 860.7(c)(2) (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 premarket approval application (PMA). (See section 520(c) of the act.)

II. Background

In the **Federal Register** of September 4, 1987 (52 FR 33686 at 33706), FDA issued a final rule classifying the hip joint metal/metal semi-constrained prosthesis with a cemented acetabular component and the hip joint metal/metal semi-constrained prosthesis with an uncemented acetabular component, (the hip joint metal/metal semi-constrained prostheses) into class III (21 CFR 888.3330 and 888.3320, respectively). In the preamble to the proposal to classify these devices (47 FR 29052, July 2, 1982), the Panel identified the following risks to health associated with use of the devices: Loss or reduction of joint function, adverse tissue reactions, and infection.

In the **Federal Register** of January 6, 1989 (54 FR 550), FDA published a notice of intent to initiate proceedings to require premarket approval for the hip joint metal/metal semi-constrained prostheses. FDA updated its priorities in the preamendments class III strategy notice of availability published in the **Federal Register** of May 6, 1994 (59 FR 23731). The agency categorized the hip joint metal/metal semi-constrained prostheses as high priority group 3 devices, devices the agency considered to have a low probability of being reclassified into class I or class II. FDA has determined that the devices identified have a high priority for initiating a proceeding to require premarket approval.

On September 25, 2000, FDA received a petition (Ref. 1) from OSMA requesting that the classification of hip joint metal/metal semi-constrained prostheses be changed from class III into class II.

III. Device Descriptions

FDA has identified the hip joint, metal/metal semi-constrained prosthesis with a cemented acetabular component and the hip joint, metal/metal semi-constrained prosthesis with a cemented acetabular component as follows: A hip joint metal/metal semi-constrained prosthesis with a cemented acetabular component, prosthesis is a two part device intended to be implanted to replace a hip joint. The device limits translation and rotation in one or more planes via the geometry of its articulation surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a femoral and an acetabular component, both made of alloys, such as cobalt-chromium-molybdenum. This generic type of device is limited to those prostheses intended for use with bone cement.

A hip joint metal/metal semi-constrained prosthesis with an uncemented acetabular component is a two part device intended to be implanted to replace a hip joint. The device limits translation and rotation in one or more planes via the geometry of its articulation surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a femoral and an acetabular component, both made of alloys, such as cobalt-chromium-molybdenum. This generic type of device is limited to those prostheses intended for use without bone cement.

IV. Recommendation of the Panel

In a public meeting on August 8, 2001, the Panel recommended five to two that the hip joint metal/metal semi-constrained prostheses not be reclassified from class III into class II (Ref. 2). The Panel concluded that the information in the petition did not demonstrate that special controls would provide reasonable assurance of safety and effectiveness of the device and that there was not sufficient information to establish special controls for the device. Specifically, the Panel determined that there was insufficient clinical and preclinical testing information to establish special controls. The Panel concluded that the length and rate of the long-term patient followup data were inadequate to demonstrate that special controls would provide reasonable assurance that the devices are safe and effective for their intended use. In addition, the Panel discussed that preclinical information, including validation of wear simulation, nonideal preclinical wear testing, and biological evaluation of metallic wear debris generated by the devices were not established. The particle size of the metallic wear debris generated by these devices is substantially smaller than the particle size of the metallic wear debris generated by other hip joint prostheses, and the short- and long-term biological effects from human retrievals or preclinical evaluation of these smaller-size metallic wear particles, are unknown. The Panel believed that premarket approval is necessary for the devices because there is insufficient information to establish that special controls would provide reasonable assurance of their safety and effectiveness.

V. FDA's Conclusion

Based on its review of the information contained in the petition and presented at the Panel meeting, as well as the Panel's discussion, the agency concurred with the Panel's recommendations. FDA agrees that there is insufficient valid scientific evidence to determine that special controls, in addition to the general controls applicable to all devices, would provide reasonable assurance of the devices' safety and effectiveness for their

intended use. The agency, therefore, is denying the petition.

VI. Reasons for the Denial

FDA has determined that the clinical and preclinical information in the petition is insufficient to support the requested change in classification of these devices. FDA believes that additional clinical data, including a longer patient followup time and a higher rate of patient followup, are necessary to develop special controls to ensure the safety and effectiveness of these devices. The agency believes that additional preclinical data, including the validation of hip simulation and nonideal wear testing of the devices at extreme loading angles, higher than normal loads, and start-stop cyclic loading, are necessary. FDA also believes that preclinical evaluation of the response to smaller sized metallic wear debris is necessary to establish special controls to provide the reasonable assurance of safety and effectiveness of the devices. FDA notes that the evaluation of the response to wear particles may include the evaluation of retrieved human devices.

In a future issue of the **Federal Register**, FDA may initiate rulemaking under section 515(b) of the act to require premarket approval for these devices. FDA notes that if new information becomes available, interested persons may submit a new reclassification petition for the devices to the agency for evaluation. FDA advises manufacturers of these device types to collect the data and information necessary to demonstrate reasonable assurance of the safety and effectiveness of their devices. This data and information should be in the form of valid scientific evidence, as defined by § 860.7, to support the least burdensome regulatory path to either remaining on the market, or entering the market for the first time. FDA believes that early data collection will more likely lead to success in obtaining premarket approval or having these device types reclassified.

VII. References

The following references have been placed on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. These references may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition for Reclassification for Metal/Metal Semi-Constrained Hip Joint Prosthesis submitted by the Orthopedic Surgical Manufacturers Association, Warsaw, IN, dated September 25, 2000, and amended on November 28, 2000, and June 4, 2001.

2. Transcript of the Orthopedic and Rehabilitation Devices Panel Meeting, August 8, 2001, pp. 1 to 244.

Dated: August 28, 2002.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 02–22688 Filed 9–5–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0325]

Medical Devices; Draft Guidance; Medical Devices Made With Polyvinylchloride Using the Plasticizer di-(2–Ethylhexyl)phthalate; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Medical Devices Made With Polyvinylchloride (PVC) Using the Plasticizer di-(2–Ethylhexyl)phthalate (DEHP); Draft Guidance for Industry and FDA.'' Through this draft guidance, FDA is proposing to offer suggestions to manufacturers who fabricate their PVC devices using the plasticizer DEHP. The guidance recommends ways that manufacturers may reduce or eliminate potential risks that may be associated with DEHP. This draft guidance is neither final nor is it in effect at this time.

DATES: Submit written or electronic comments on this guidance by December 5, 2002.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Medical Devices Made With Polyvinylchloride (PVC) Using the Plasticizer di-(2–Ethylhexyl)phthalate (DEHP); Draft Guidance for Industry and FDA'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written comments concerning this guidance 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: Robert Gatling, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

SUPPLEMENTARY INFORMATION:

I. Background

DEHP is recognized as an important chemical ingredient that affords PVC many of the physical properties that make the material optimally suited for use in many of today's medical devices. DEHP is a chemical whose long-term effects on the human body are unknown. In this draft guidance, FDA is suggesting that manufacturers label certain devices with their DEHP content and consider eliminating the use of DEHP in certain devices that can result in high aggregate exposures in sensitive patient populations.

FDA recognizes that many devices with PVC containing DEHP are not used in ways that result in significant human exposure to the chemical. Therefore, this draft guidance focuses on the small subset of medical devices where PVC containing DEHP may come in contact with the tissue of a sensitive patient population in a manner and for a period of time that may raise concerns about the aggregate exposure to DEHP.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on medical devices made with PVC using the plasticizer DEHP. 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 used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

In order to receive the ''Medical Devices Made With Polyvinylchloride (PVC) Using the Plasticizer di-(2–Ethylhexyl)phthalate (DEHP); Draft Guidance for Industry and FDA'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1407) followed by the pound