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

sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Dockets Management Branch Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Comments

You may submit to the Dockets Management Branch (*see* **ADDRESSES**) written or electronic comments regarding this draft guidance by December 5, 2002. You must submit two copies of any comments. Individuals may submit one copy. You must identify comments with the docket number found in brackets in the heading of this document. The draft guidance document and any received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 28, 2002.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 02–22687 Filed 9–5–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR 4736–N–13)

Notice of Proposed Information Collection for Public Comment for Report on Occupancy for Public and Indian Housing

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments Due Date: November 5, 2002.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control number and should be sent to: Mildred M. Hamman, Reports Liaison Officer, Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street, SW., Room 4249, Washington, DC 20410–5000.

FOR FURTHER INFORMATION CONTACT: Mildred M. Hamman, (202) 708–0614, extension 4128, for copies of the proposed forms and other available documents. (This is not a toll-free number).

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Report on Occupancy for Public and Indian Housing.

OMB Control Number: 2577–0028.

Desription of the need for the information and proposed use: Housing Agencies (HAs) are required to submit occupancy information to HUD electronically for monitoring dwelling, nondwelling, demolished, boarded-up, under repair/modernization rehabilitation or vacant units. THe information should be verified on the Form HUD–51234 before it is submitted electrtonically. The information enables HUD to monitor the rate and extent at which the Low-income Public Housing Program is being used by HAs to assist low-income families.

Agency form number: HUD–51234.

Members of affected public: State, Tribal or Local Government.

Estimation of the total number of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: 3400 respondents. Report period end date which shall be the date which is the last day of the month ending six months before the start of the PHA's Requested Budget. Year (BBY), one hour average per response; total annual reporting burden 3400 hours.

Status of the proposed information collection: Reinstatement, without change.

Authority: Section 3506 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: September 3, 2002.

Michael Liu,

Assistant Secretary for Public and Indian Housing.

BILLING CODE 4210–33–M