SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 23, 2004 (69 FR 3372), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0298. The approval expires on March 31, 2007. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets.*

Dated: April 6, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–8305 Filed 4–12–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0154]

Medical Devices; Semicritical Reprocessed Single-Use Devices; Termination of Exemptions From Premarket Notification; Requirement for Submission of Validation Data

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of semicritical reprocessed single-use devices (SUDs) whose exemption from premarket submission is being terminated and for which validation data, as specified under the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), are necessary in a premarket notification (510(k)). FDA is requiring submission of these data to ensure that these reprocessed SUDs are substantially equivalent to predicate devices in accordance with MDUFMA.

DATES: These actions are effective April 13, 2004. Manufacturers of reprocessed SUDs identified in the list whose exemptions are being terminated must submit 510(k)s for these devices by July 13, 2005, or these devices may no longer be legally marketed.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.* Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Barbara A. Zimmerman, 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

On October 26, 2002, MDUFMA (Public Law 107–250) amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 510(o) (21 U.S.C. 360(o)), which provided new regulatory requirements for reprocessed SUDs. According to this new provision, 510(k)s for certain reprocessed SUDs identified by FDA must include validation data to ensure that the reprocessed SUDs are substantially equivalent to predicate devices. The required validation data include cleaning and sterilization data, and functional performance data demonstrating that each SUD will remain substantially equivalent to its predicate device after the maximum number of times the device is reprocessed as intended by the person submitting the premarket notification.

Before the enactment of the new law, the agency required a manufacturer of a reprocessed SUD to obtain premarket approval or premarket clearance for the device, unless the device was exempt from premarket submission requirements. Under MDUFMA, some previously exempt critical and semicritical reprocessed SUDs will no longer be exempt from premarket notification requirements. Manufacturers of these identified devices will need to submit 510(k)s that include validation data as specified by FDA.

Under section 302(b) of MDUFMA, a reprocessed SUD is defined as an

> "original device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient. The subsequent processing and manufacture of a reprocessed single-use device shall result in a device that is reprocessed within the meaning of this definition.''

Reprocessed SUDs are divided into the following three categories: (1) Critical, (2) semicritical, and (3) noncritical. The first two categories reflect definitions contained in MDUFMA, and all three reflect a classification scheme recognized in the industry.[1] These categories of devices are defined as follows:

1. A *critical reprocessed SUD* is intended to contact normally sterile tissue or body spaces during use.

2. A *semicritical reprocessed SUD* is intended to contact intact mucous membranes and not penetrate normally sterile areas of the body.

3. A *noncritical reprocessed SUD* is intended to make topical contact and not penetrate intact skin.

In the **Federal Register** of April 30, 2003 (68 FR 23139), FDA explained its methodology and criteria for determining which device types should no longer be exempt from premarket submission requirements in accordance with MDUFMA. As described in the April 2003 **Federal Register** notice, in the first step of this process, the agency categorized all known types of SUDs that were being reprocessed as critical, semicritical, or noncritical using the previously listed definitions. Next, FDA evaluated the overall risk (high, moderate, or low) associated with the reprocessed SUDs using the review prioritization scheme (RPS) that had been previously described in a draft guidance document.[2] In the RPS guidance, FDA set forth factors that could be used to evaluate the risk associated with reprocessed SUDs and assign an overall risk to each SUD based on the risk of the following: (1) Infection and (2) inadequate performance following reprocessing. The designation of "high risk'' was assigned to those devices that posed the greatest risk of infection and inadequate performance after reprocessing.

In addition to the previously listed steps, FDA also identified all reprocessed SUDs intended to come in contact with tissue at high risk of being infected with the causative agents of Creutzfeldt-Jakob Disease (CJD). As stated in the April 2003 **Federal Register** notice, these are generally devices intended for use in neurosurgery and ophthalmology. This criterion was used in FDA's evaluation because insufficient scientific information exists at this time to establish standard methods to eliminate CJD infectious agents.

---

[1] Spaulding, E. H., "The Role of Chemical Disinfection in the Prevention of Nosocomial Infections,'' P. S. Brachman and T. C. Eickof (ed), Proceedings of International Conference on Nosocomial Infections, 1970, American Hospital Association, Chicago, 1971:254–274.

[2] The draft guidance entitled "Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme'' (appendix 2 superseded) is available on the Center for Devices and Radiological Health's (CDRH) Web site at *http://www.fda.gov/cdrh/reuse/1156.pdf.*

Using this process and criteria, FDA developed a reference list (attachment 1 of the April 2003 **Federal Register** notice). This list identifies the entire group of reprocessed SUDs, and the levels of risk associated with the devices, that FDA considered when implementing the new statutory requirements in section 510(o) of the act. (For more detailed information on the process FDA used to identify these SUDs and assign risk categorizations, see 68 FR 23139.)

II. Requirements for 510(k) Exempt Critical Reprocessed SUDs

In the April 2003 **Federal Register** notice, as required by MDUFMA, FDA published a list of critical reprocessed SUDs whose exemptions from premarket submission were being terminated and for which validation data in 510(k) submissions would be necessary. In the notice, FDA identified those critical reprocessed SUDs that were either ''high'' risk, as described previously, or intended to come in contact with tissue at high risk of being infected with the causative agents of CJD (see list I of the April 2003 **Federal Register** notice). FDA also published a revised version of this list in the **Federal Register** of June 26, 2003 (68 FR 38071).

III. Requirements for 510(k) Exempt Semicritical Reprocessed SUDs

As discussed previously, MDUFMA also requires FDA to review the semicritical reprocessed SUDs that are currently exempt from premarket notification requirements and determine which of these devices will require 510(k)s with validation data in order to ensure their substantial equivalence to predicate devices. FDA is required to identify these devices in a notice published in the **Federal Register** by April 26, 2004. The attached list of semicritical reprocessed SUDs implements this MDUFMA requirement. Using the methodology and criteria described in this document for developing the list of critical reprocessed SUDs, the agency determined which semicritical reprocessed SUDs should be subject to premarket submission requirements. All devices identified in the attached list have been determined to be high risk semicritical reprocessed SUDs. It should be noted that not all exempt semicritical devices have been listed. Semicritical reprocessed SUDs that are not listed at this time may be added to future updates of the list.

As required by MDUFMA, manufacturers of the devices identified in the attached list must submit 510(k)s that include validation data regarding cleaning, sterilization, and functional performance, in addition to all the other required elements of 510(k)s identified in 21 CFR 807.87, within 15 months of publication of this notice or they may no longer legally market these devices after that date.

LIST 1.—SEMICRITICAL REPROCESSED SINGLE-USE DEVICES PREVIOUSLY EXEMPT FROM PREMARKET NOTIFICATION REQUIREMENTS THAT WILL NOW REQUIRE 510(K)S WITH VALIDATION DATA

21 CFR Section	Classification Name	Product Code for Non-reprocessed Device	Product Code for Reprocessed Device	Product Code Name for Reprocessed Device
872.5410	Orthodontic appliance and accessories	EJF	NQS	Orthodontic metal bracket
876.4680	Ureteral stone dislodger	FGO, FFL	NQT, NQU	Flexible and basket stone dislodger
868.6810	Tracheobronchial suction catheter	BSY	NQV	Tracheobronchial suction catheter

IV. Requirements for 510(k) Exempt Noncritical Reprocessed SUDs

MDUFMA does not require FDA to take any action under section 510(o) of the act for noncritical reprocessed SUDs that are exempt from premarket submission requirements.

V. Stakeholder Input

In the **Federal Register** of February 4, 2003 (68 FR 5643), FDA invited interested persons to provide information and share views on the implementation of MDUFMA. Since that time, the agency has received comments on various MDUFMA provisions, including several on its implementation of section 510(o) of the act. One comment expressed concern about the agency's reliance on the Review Prioritization Scheme (RPS). According to the comment, the RPS is a subjective and incomplete method for accurately assessing the risk associated with reprocessing. The comment further stated that Congress's intent was for the Spaulding criteria to be the primary mechanism used to determine whether the exempt status of reprocessed SUDs remains appropriate.

As stated in the April 30, 2003 **Federal Register** notice, the agency continues to believe that the RPS is an appropriate risk-based tool for identifying those devices that are likely to raise concerns about both infection transmission and inadequate performance following reprocessing. FDA believes that the flowchart that is part of the RPS provides an objective, science-based assessment of these risks for each type of reprocessed device. In addition, while MDUFMA defines the terms ''critical reprocessed single-use device'' and ''semi-critical reprocessed single-use device'' in new section 201(mm)(1) and (mm)(2) of the act, new section 510(o)(2)(A) states that ''[t]he Secretary shall identify such devices or types of devices for which such exemptions should be terminated in order to provide a reasonable assurance of the safety and effectiveness of the devices.'' Given this statutory language, FDA believes that while Congress used the Spaulding definitions to initially categorize reprocessed SUDs, Congress also authorized the agency to apply additional criteria in determining the devices for which 510(k) exemptions should be terminated.

The agency also received a comment that identified specific reprocessed SUDs whose exemption from the 510(k) requirements should be terminated. The agency considered these recommendations while finalizing this document. Although this list of semicritical reprocessed SUDs does not include all of those devices that were recommended in the comment, the agency believes that 510(k)s with validation data should be required in accordance with MDUFMA for the devices identified on the list due to concerns about infection transmission and performance. As stated in the April 2003 **Federal Register** notice, the agency recognizes that the lists of critical and semicritical devices may need to be reevaluated and updated over time. Therefore, FDA will consider comments from the public on additional devices

that should be included on the lists at any time.

Finally, FDA would like to take this opportunity to remind entities that reprocess SUDs of the guidance document entitled "Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions [510(k)s] for Reprocessed Single-Use Medical Devices.'' FDA announced the availability of this guidance in the **Federal Register** of July 8, 2003 (68 FR 40679). This guidance document provides FDA's recommendations for manufacturers of reprocessed SUDs to assist them in complying with MDUFMA's validation data submission requirement and should be helpful to manufacturers of those semicritical reprocessed SUDs listed below in preparing their 510(k)s. This guidance may be found on CDRH's Web site at *http://www.fda.gov/cdrh/guidance/html*.

VI. Paperwork Reduction Act of 1995

This document contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information described in this document were approved under OMB control number 0910–0514.

VII. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document at any time. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 5, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–8307 Filed 4–12–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Fifth Joint Project Management Workshop on Improving Agency/Industry Communication Throughout the Drug Development Process; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) in cosponsorship with the Drug Information Association (DIA) is announcing a public workshop entitled "The Fifth Joint Project Management Workshop: Improve Agency/Industry Communication Throughout the Drug Development Process.'' The workshop will focus on facilitating the drug development and drug review processes through interactions between industry and FDA to effectively manage risk to expedite products of public benefit to market.

Date and Time: The public workshop will be held on May 11, 2004, from 8:30 a.m. to 5 p.m., May 12, 2004, from 8:30 a.m. to 5 p.m., and May 13, 2004, from 8:30 a.m. to 12:30 p.m.

Location: The public workshop will be at the Hyatt Regency Bethesda, 1 Bethesda Metro Center, Bethesda, MD.

Contact Person: Julieann Dubeau, Center for Drug Evaluation and Research (HFD–180), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD, 301–827–7310, FAX: 301–827–1305, e-mail: *Dubeau@cder.fda.gov*, or Gail Sherman, Center for Biologics Evaluation and Research (HFM–42), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–2000, FAX: 301–827–3079, e-mail: *Sherman@cber.fda.gov*, or Camela Pastorius, Drug Information Association, 800 Enterprise Rd., suite 200, Horsham, PA 19044, 215–442–6196, FAX: 215–442–6103, e-mail: *Camela.Pastorius@diahome.org*.

Registration: Mail or fax your registration information and registration fee to Drug Information Association (DIA), P.O. Box 827192, Philadelphia, PA 19182–7192. You may obtain registration forms from DIA (see *Contact Person*) or from FDA at *http://www.fda.gov/cber/meetings.htm*. Additional information regarding registration fees and online registration can be found at *http://www.diahome.org/docs/events/events__search__detail.cfm*. (FDA has verified the Web site, but we are not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

If you need special accommodations due to a disability, please contact Camela Pastorius (see *Contact Person*) by May 4, 2004.

SUPPLEMENTARY INFORMATION: FDA (the Center for Biologics Evaluation and Research and the Center for Drug Evaluation and Research) and DIA are cosponsoring a public workshop as part of a continuing effort to develop higher levels of teamwork, communication, and procedural knowledge to facilitate drug development and review in the United States. The workshop's target audience is project directors, leaders, managers, and regulatory affairs representatives from industry; and FDA reviewers, regulatory project managers, and consumer safety officers. At the conclusion of the workshop, the participants should be able to do the following: (1) Identify FDA/industry cultural differences that influence interactions between the two groups, (2) effectively manage constructive interactions in a changing environment, and (3) manage communication strategies for facilitating drug approvals.

Dated: April 6, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–8251 Filed 4–12–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1999D–2335]

Guidance for Industry and Food and Drug Administration Staff; Premarket Approval Applications for Absorbable Powder for Lubricating a Surgeon's Glove; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Premarket Approval Applications (PMA) for Absorbable Powder for Lubricating a Surgeon's Glove.'' This guidance describes the information FDA recommends that you provide in a PMA for absorbable powder for lubricating a surgeon's glove.

DATES: Submit written or electronic comments on this guidance at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the