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