

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D-0309]

**Guidance for Industry and Food and Drug Administration Staff; Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions for Reprocessed Single-Use Medical Devices; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

---

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the revised guidance entitled "Guidance for Industry and FDA Staff; Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices" (validation data guidance). This guidance document is being revised to include the procedures and timeframes that the agency intends to follow in its review of the validation data required by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), for certain reprocessed single-use devices (SUDs), to include updated references to relevant **Federal Register** notices, and to include a section addressing the Paperwork Reduction Act of 1995 (the PRA). This guidance document is immediately in effect, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

**DATES:** Submit written or electronic comments on this guidance at any time.  
ch0431

2003D-0309

DDM

Display Date 5-26-04 @ 3:59pm

Publication Date 6-1-04

Certifier A. Corbin

NAD 1

**ADDRESSES:** Submit written requests for single copies on a 3.5" diskette of the guidance document entitled "Guidance for Industry and FDA Staff; Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label 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 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:** Timothy A. Ulatowski, Center for Devices and Radiological Health (HFZ-300), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-4692.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Section 302(b) of MDUFMA (Public Law 2003D-0309) added new requirements for reprocessed SUDs to section 510(o) of the act (21 U.S.C. 360(o)). One of these provisions required FDA to review the reprocessed SUDs that were exempt from premarket notification requirements and to determine which of these devices require the submission of 510(k)s with validation data to ensure their substantial equivalence to predicate devices. The new law also

requires the submission of validation data specified in the statute for certain reprocessed SUDs, identified by FDA, that were already subject to 510(k) submission requirements when MDUFMA was enacted. The types of validation data to be submitted include cleaning, sterilization, and functional performance data.

On July 8, 2003, FDA issued guidance under the same title describing the types of validation data that FDA recommended be submitted to the agency to support a substantial equivalence determination for the reprocessed SUDs for which validation data are required by MDUFMA. FDA is now revising the guidance to include the review procedures and timeframes the agency intends to follow when processing the required validation data. This guidance supersedes the July 8, 2003, document.

FDA is implementing this level 1 guidance upon issuance because it is essential for the agency to provide immediate guidance on the procedures and timeframes that FDA intends to follow in reviewing the validation data required by MDUFMA. The agency has determined that, in light of the need to provide immediate guidance to manufacturers of reprocessed SUDs, a request for comments before issuance of this revised guidance is not feasible. FDA is also considering additional changes to the validation guidance based on comments and questions received since this guidance was initially implemented. These changes would be incorporated into a future revision of the guidance.

## **II. Significance of Guidance**

This guidance is being issued consistent with FDA's GGP's regulation (21 CFR 10.115). The guidance represents the agency's current thinking on validation data regarding the cleaning, sterilization, and functional

performance of reprocessed SUDs, as well as the procedures and review times that should be used by FDA in evaluating these validation data. 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

To receive “Guidance for Industry and FDA Staff; Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices” by fax machine, call the Center for Devices and Radiological Health (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 (Office GGP Rep will insert DOC number) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by 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>.

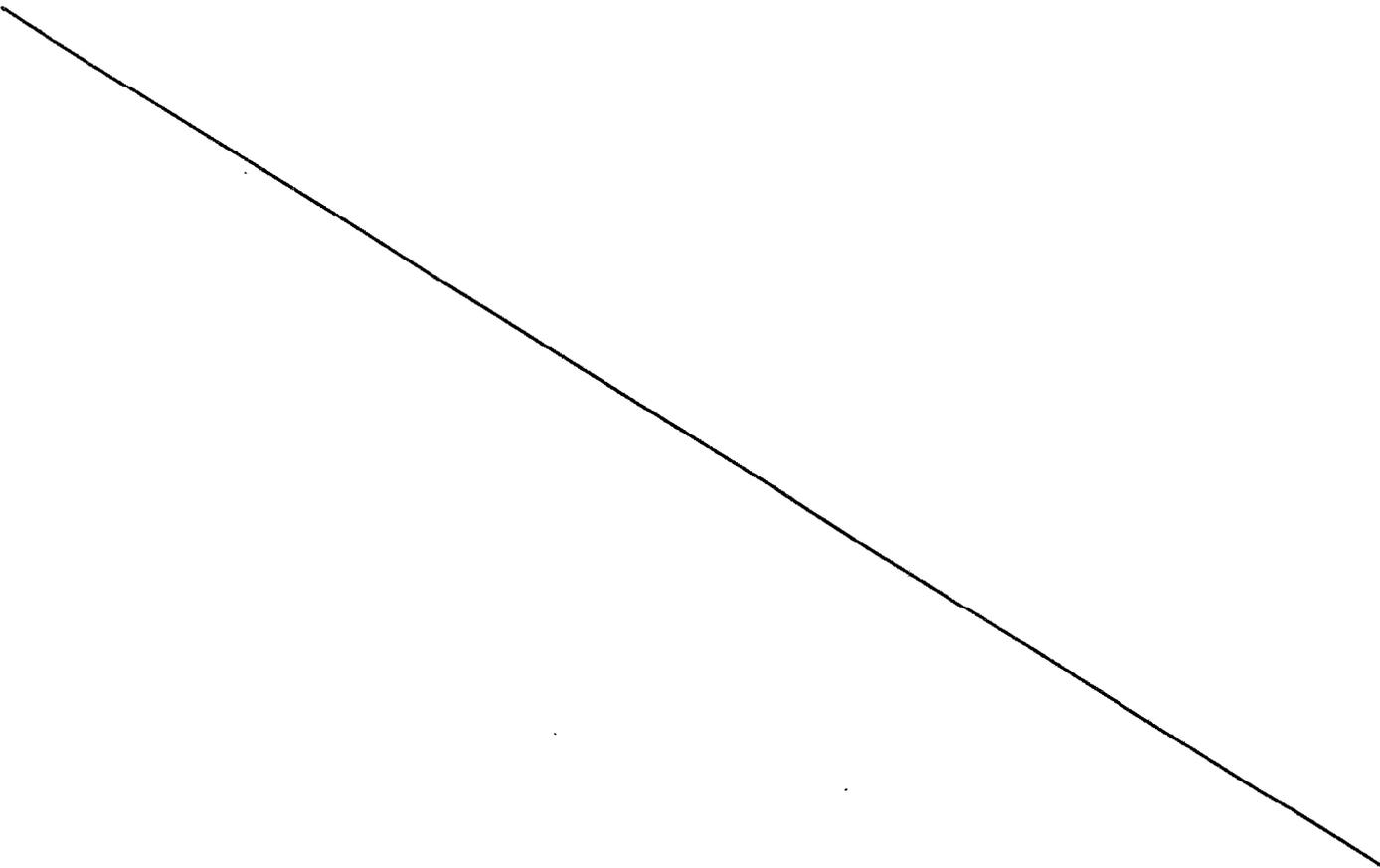
Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

#### **IV. Paperwork Reduction Act of 1995**

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the PRA (44 U.S.C. 3501–3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910–0120).

#### **V. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments>. Submit 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.  
Comments received may be seen in the Division of Dockets Management  
between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 5/25/04

May 25, 2004.



---

Jeffrey Shuren,  
Assistant Commissioner for Policy.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

**BILLING CODE 4160-01-S**

