DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families Statement of Organization, Functions and Delegations of Authority

Notice is hereby given that I delegate to the Commissioner, Administration on Developmental Disabilities, with authority to further redelegate, the following authority vested in the Assistant Secretary for Children and Families by the Secretary under the Developmental Disabilities Assistance and Bill of Rights Act of 2000, Pub.L. 106–402, 114 Stat. 1677 (2000), 42 U.S.C. 15001 *et seq*.

(a) Authority Delegated

Authority to administer the Developmental Disabilities Assistance and Bill of Rights Act of 2000, (The Act), Pub. L. 106–402, 114 Stat. 1677 (2000), 42 U.S.C. 15001 *et seq*., and as amended, hereafter, including authority to make the initial decision regarding withholding of funds from States pursuant to section 127 of the Act (42 U.S.C. 15027).

(b) Effect on Existing Delegations

Replaces.

(c) Limitations

1. This delegation shall be exercised under the Department's existing delegation and policy on regulations.

2. This delegation does not include authority to hear appeals under 45 CFR 1386, subpart D, 45 CFR 1386.20(e), or 45 CFR 1386.34(d).

3. This delegation shall be exercised under financial and administrative requirements applicable to all Administration for Children and Families authorities.

4. I hereby affirm and ratify any actions taken by the Commissioner, Administration on Developmental Disabilities, or any other Administration on Developmental Disabilities officials, which, in effect, involved the exercise of this authority prior to the effective date of this delegation.

5. Any redelegation shall be in writing and prompt notifications must be provided to all affected managers, supervisors, and other personnel.

(d) Effective Date

This delegation is effective immediately.

Dated: April 2, 2004.

Wade F. Horn,

Assistant Secretary for Children and Families.

[FR Doc. 04–8336 Filed 4–12–04; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0482]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Mammography Facilities, Standards, and Lay Summaries for Patients

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Mammography Facilities, Standards, and Lay Summaries for Patients'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 9, 2004 (69 FR 5991), 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 0910–0309. 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 2, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–8250 Filed 4–12–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0424]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Substantial Evidence of Effectiveness of New Animal Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Substantial Evidence of Effectiveness of New Animal Drugs'', has been approved by the Office of Management and Budget (OMB) under provisions of the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 7, 2004 (69 FR 923), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (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 0910–0356. The approval expires on March 31, 2007.

Dated: April 6, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–8252 Filed 4–12–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0397]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Threshold of Regulation for Substances Used in Food-Contact Articles

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Threshold of Regulation for Substances Used in Food-Contact Articles'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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.*