DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0500]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Requirements for Collection of Data Relating to the Prevention of Medical Gas Mixups at Health Care Facilities—Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ≥Requirements for Collection of Data Relating to the Prevention of Medical Gas Mixups at Health Care Facilities—Survey≥ has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Liz Berbakos, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 25, 2006 (71 FR 30146), 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 0910–0548. The approval expires on August 31, 2008. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: August 10, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Heparin Catheter Lock-Flush Solutions; Transfer of Primary Responsibility from Center for Drug Evaluation and Research to Center for Devices and Radiological Health

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; announcement of transfer.

SUMMARY: The Food and Drug Administration (FDA) is announcing the transfer of primary responsibility for the regulation of heparin catheter lock-flush solution products from the Center for Drug Evaluation and Research (CDER) to the Center for Devices and Radiological Health (CDRH). These products are combination drug-device products. The transfer of lead review responsibility to CDRH is based on FDA's determination that the primary mode of action for these heparin catheter lock-flush solution products is that of the device part of the combination. The transfer provides consistency and efficiency in the regulation of these combination products by treating like products similarly.

DATES: The effective date of the transfer is October 16, 2006.

FOR FURTHER INFORMATION CONTACT:

For information regarding this notice: James S. Cohen, Office of the Commissioner (HFG–3), Food and Drug Administration, 15800 Crabbs Branch Way, Rockville, MD 20855, 301–427–1934.

For questions on what to submit in the 510(k) submission: Sheila A. Murphe, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., rm. 350AA, Rockville, MD 20850, 301–443–8913, ext. 203.

SUPPLEMENTARY INFORMATION: Heparin catheter lock-flush solution products are intended to enhance the performance of intravascular catheters. An intravascular catheter is a device that consists of a slender tube and any necessary connecting fittings that are inserted into a patient's vascular system for short-term use (less than 30 days) to sample blood, monitor blood pressure, or administer fluids intravenously. Heparin catheter lock-flush solutions are periodically inserted into and stored within the catheter to keep the catheter patent and to prevent blood from clotting within the catheter between uses.

Prior to the mid-1990's, heparin catheter lock-flush solution products were regulated under the new drug and abbreviated new drug provisions of the Federal Food, Drug, and Cosmetic Act (the act), with CDER serving as the lead agency review component. Many of the available marketed products were approved under abbreviated new drug applications (''generic drugs''). However, more recently, based on several jurisdictional determinations by FDA for specific products, applications for catheter lock-flush solutions containing anticoagulant, such as heparin, or antimicrobial components have been assigned to CDRH and regulated under the device provisions of the act. FDA is now transferring the applications for heparin catheter lock-flush solution products that are in CDER to reflect these more current jurisdictional determinations.

Heparin catheter lock-flush solutions are intended to maintain patency when the catheter is not being used to sample blood, monitor blood pressure, or administer fluids to the patient. The solution component of the product (i.e., sterile saline or sterile water) acts by physically occupying space within the intravenous catheter and exerting pressure on the patient's circulating blood. This action helps to prevent the patient's blood from backfilling into the catheter, clotting, and contributing to microbial contamination. When acting in this way, the solution meets the definition of a device in the act in that it affects the structure or function of the body, and does not achieve its primary intended purposes through chemical or metabolic action (21 U.S.C. 321(h)). Likewise, the heparin (i.e. the anticoagulant) component of the product meets the definition of a drug in that it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man, and is intended to affect the structure or function of the body of man (21 U.S.C. 321(g)).

Catheter lock-flush solutions that contain both drug and device components are combination products as defined in 21 CFR 3.2(e)(1). FDA is responsible for assigning combination products to a lead agency Center for regulation based upon the agency's determination of the combination product's ''primary mode of action.'' (See 21 U.S.C. 353(g)(1) and 21 CFR 3.4.) FDA has determined that the primary mode of action of heparin catheter lock-flush solution products in maintaining catheter patency is attributable to the device component's role in physically occupying space and applying pressure within the catheter.