

• Establishment type: Query has been made of CDRH's registration/listing databank and has counted 8,188 domestic firms subject to CGMPs. In addition, hospitals which reuse or remanufacture devices are now considered manufacturers under new FDA guidance. During the last report, it was estimated that out of the 6,000 hospitals in the United States, one third of them (or 2,000 hospitals) will reuse or remanufacture single use medical devices. After investigations of many hospitals and the changes in enforcements of FDA's requirements for hospitals, the number of reuse or remanufactures of single-use medical devices have decreased from the estimated 2,000 to an estimated 66 hospitals. Thus, the number of manufacturers will increase from 7,229 to 8,188, but the total number of firms subject to CGMPs will decrease from 9,229 to 8,254.

• Potentially affected establishments: Except for manufacturers, not every type of firm is subject to every CGMP/QS requirement. For example, all are subject to FDA's quality policy regulations (§ 820.20(a)), document control regulations (§ 820.40), and other requirements, whereas only manufacturers and specification developers are subject to FDA's design controls regulations (§ 820.30). The type of firm subject to each requirement was identified by ERG.

FDA estimated the burden hours (and costs) for the previous CGMP regulation in 1992. That estimate was submitted to OMB on May 4, 1992. It was approved by OMB on July 16, 1992, and expired on June 30, 1995. The methodology used is different than that used by ERG in estimating incremental tasks when the new CGMP/QS became final. Nevertheless, the agency believes its 1992 estimate adequately represents labor hours (and costs) needed to comply with previous CGMP requirements carried over into the new CGMP/QS regulation. The 1992 estimate used 9,289 respondents (rather than 8,254 respondents), which compensates for differences in methodology.

FDA estimates that some 650 "new" establishments (marketing devices for the first time) will expend some 143,052 "development" hours on a one-time startup basis to develop records and procedures for the CGMP/QS regulation.

FDA estimates that annual labor hours are apportioned as follows: 40 percent goes to requirements dealing with manufacturing specifications, process controls and the DHR; 20 percent goes to requirements dealing with components and acceptance activities; 25 percent goes to requirements dealing

with equipment, records (the DMR and QSR), complaint investigations, labeling/packaging and reprocessing/investigating product nonconformance; and 15 percent goes to quality audit, traceability, handling, distribution, statistical, and other requirements.

Dated: June 4, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0425]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed" has been approved by the Office of Management and Budget (OMB) under 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 16, 2004 (69 FR 2602), 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 0910-0339. The approval expires on May 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: June 4, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0542]

Agency Information Collection Activities; Announcement of OMB Approval; Premarket Notification Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Premarket Notification Submissions" 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 March 9, 2004 (69 FR 11022), 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 0910-0120. The approval expires on May 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: June 4, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0245]

Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practice Regulations for Medicated Feeds

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.