

above, and must be received on or before Friday, August 12, 2005.

Donald S. Clark,
Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0045]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Electronic Records; Electronic Signatures

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Electronic Records; Electronic Signatures" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, 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 11, 2005 (70 FR 24818), 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 0910-0303. The approval expires on July 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: July 27, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05-15544 Filed 8-5-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0031]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Premarket Notification for a New Dietary Ingredient

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 for a New Dietary Ingredient" 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 May 3, 2005 (70 FR 22886), 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 0910-0330. The approval expires on July 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: July 27, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D-0288]

International Conference on Harmonisation; Draft Guidance on Q9 Quality Risk Management; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Q9 Quality Risk Management." The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guidance provides principles and examples of tools for quality risk management that can be applied to all aspects of pharmaceutical quality throughout the lifecycle of drug substances, drug products, and biological and biotechnological products. The draft guidance is intended to enable regulators and industry to make more effective and consistent risk-based decisions.

DATES: Submit written or electronic comments on the draft guidance by October 7, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written comments on the draft 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>. Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training, and Manufacturers Assistance (HFMA-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. The draft guidance may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800. Send two self-addressed adhesive labels to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: David J.

Horowitz, Center for Drug Evaluation and Research (HFD-300), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-8910; Anna M. Flynn, Center for Biologics Evaluation and Research (HFMA-610), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-6201; Diana J. Kolaitis, Office of Regulatory Affairs (HFR-NE1), Food and Drug Administration,