

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**Food and Drug Administration**

[Docket No. 2000D-1318]

**Guidance for Industry on Chronic Cutaneous Ulcer and Burn Wounds—Developing Products for Treatment; Availability**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled “Chronic Cutaneous Ulcer and Burn Wounds—Developing Products for Treatment.” This document provides recommendations on developing products for the treatment of chronic cutaneous ulcer and burn wounds. It includes general guidance on clinical trial design as well as preclinical and manufacturing considerations. This guidance finalizes the draft guidance published on June 28, 2000.

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of this 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 (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. Submit written comments on the 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>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:**

Elektra Papadopoulos, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 5189, Silver Spring, MD 20993-0002, 301-796-2110; or Susan Leibenhaut, Center for

Biologics Evaluation and Research (HFM-755), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-6536; or

Charles N. Durfor, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-3090.

**SUPPLEMENTARY INFORMATION:**
**I. Background**

FDA is announcing the availability of a guidance for industry entitled “Chronic Cutaneous Ulcer and Burn Wounds—Developing Products for Treatment.” On June 28, 2000 (65 FR 39912), FDA published for comment in the **Federal Register** a draft of this guidance. The guidance addresses the development of drugs, biological products, and medical devices for the treatment of burn wounds and chronic cutaneous ulcers, including venous stasis ulcers, diabetic foot ulcers, and pressure ulcers. Included are recommendations for trial design, labeling claims, outcome measures, and special considerations for preclinical development, as well as for manufacturing.

Comments received from industry, professional societies, and consumer groups on the draft guidance have been taken into consideration by FDA in finalizing this guidance and some of the changes are summarized here. The accelerated wound closure section has been modified and now indicates that if claims are sought for both increased incidence of wound closure and accelerated healing, then the study should be designed to detect both effects. The section on debridement outcomes has been clarified and indicates clinically relevant endpoints for debriding agents. Newly addressed are wound pain amelioration outcomes, outcomes for temporary dressings, and recommendations for choosing lesions for evaluation of efficacy outcomes (e.g., target lesion or complete healing of all lesions reported per patient).

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). This guidance represents the agency’s current thinking on developing products for the treatment of chronic cutaneous ulcer and burn wounds. 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 statutes and regulations.

**II. 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 or 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

**III. Electronic Access**

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm>, <http://www.fda.gov/cber/guidelines.htm>, or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: May 23, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**Food and Drug Administration**

[Docket No. 2005D-0288]

**International Conference on Harmonisation; 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 guidance entitled “Q9 Quality Risk Management.” The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The 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 guidance is intended to enable regulators and industry to make more effective and consistent risk-based decisions.

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

**ADDRESSES:** Submit written comments on the 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 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 (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. Send two self-addressed adhesive labels to assist the office in processing your requests. Requests and comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:**

*Regarding the guidance:* H. Gregg Claycamp, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 301-827-6505; Albinus D Sa, Center for Drug Evaluation and Research (HFD-320), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-9044; Anna M. Flynn, Center for Biologics Evaluation and Research (HFM-610), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-6201; or Diana J. Kolaitis, Office of Regulatory Affairs (HFR-NE1), Food and Drug Administration, 158-15 Liberty Ave., Jamaica, NY 11433, 718-662-5612.

*Regarding the ICH:* Michelle Limoli, Office of International Programs (HFG-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4480.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance

harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research; FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In the **Federal Register** of August 8, 2005 (70 FR 45722), FDA published a notice announcing the availability of a draft tripartite guidance entitled "Q9 Quality Risk Management." The notice gave interested persons an opportunity to submit comments by October 7, 2005.

After consideration of the comments received and revisions to the guidance, a final draft of the guidance was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies in November 2005.

The guidance provides recommendations for a systematic approach to quality risk management. The guidance is intended to support other ICH quality documents, complement existing quality practices and standards, and enable regulators and industry to make more effective and consistent risk-based decisions.

The guidance includes principles and examples of tools for quality risk management that can be applied to different aspects of pharmaceutical

quality throughout the lifecycle of drug substances, drug products, and biological and biotechnological products. These aspects include development, manufacturing, distribution, inspection, and submission/review processes (including the use of raw materials, solvents, excipients, packaging and labeling materials in drug products and biological and biotechnological products). The guidance is not intended to create any new expectations beyond current regulatory requirements.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on this topic. 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 statutes and regulations.

**II. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance at any time. Submit a single copy of electronic comments or 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. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

**III. Electronic Access**

Persons with access to the Internet may obtain the document at <http://www.fda.gov/ohrms/dockets/default.htm>, <http://www.fda.gov/cder/guidance/index.htm>, or <http://www.fda.gov/cber/publications.htm>.

Dated: May 23, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute of Neurological Disorders and Stroke; Amended Notice of Meeting**

Notice is hereby given of a change in the meeting of the Neurological Sciences and Disorders A, June 22,