

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 This guidance finalizes the draft guidance published on June 28, 2000.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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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.