



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Public Health Service

National Institutes of Health
Bethesda, Maryland 20892
Building: 30
Room: 414
Telephone: (301) 496-4069
Fax : (301) 402-0897

Date: October 23, 2001

To: FDA

From: Chief, Cell Biology Section, NIH, NIDCR

Subject: FDA draft Guidance for industry: chronic cutaneous ulcer and burn wounds-developing products for treatment

I am writing about the draft document "Guidance for industry: chronic cutaneous ulcer and burn wounds-developing products for treatment" which appeared in the latest issue of Wound Repair and Regeneration. I am a basic researcher in the wound repair field and have concerns about the draft document. I was particularly bothered by the preclinical considerations. Much of the language is vague (ie. "should include", "are helpful", "is recommended" etc) and it is not clear how much (any or all or some?) of the "Guidance" must be followed. This is confusing language and appears to impose huge restraints (may discourage) on product development for a growing population with an unmet need. I understand the complexity of the wound field and various treatment options and feel that the material presented could be improved upon to make it more useful to everyone. I would like to suggest that the FDA work with academic leaders together (in the same room) to formulate a working document that is more helpful to the community. Documents like this should be encouraging academia and industry to develop and test more products but that is not perceived in this "guidance". This should be a "partnership" with the FDA for guidelines for the safest and newest treatments that will benefit a large population.

Hynda K. Kleinman, Ph.D.

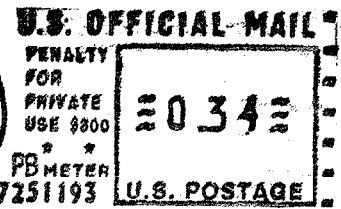
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