

PURDUE

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August 25, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

**RE: Docket No. 00D-1318, CDER 9952
Comments on the Draft "Guidance for Industry: Chronic Cutaneous Ulcer
and Burn Wounds – Developing Products for Treatment"**

Dear Sir/Madam,

The Purdue Frederick Company respectfully submits the attached comments on the draft guidance document referenced above. These comments were prepared in response to the solicitation of comments for the draft guidance of June 28, 2000 notice of availability published in the Federal Register.

Please contact the undersigned with questions concerning this submission.

Sincerely,
The Purdue Frederick Company
By:

David W. Grob

David W. Grob, MS, RAC
Associate Director, Regulatory Affairs and Labeling

Enclosures

00D-1318

C 4

Comments On

DRAFT GUIDANCE FOR INDUSTRY.
CHRONIC CUTANEOUS ULCER AND BURN WOUNDS-
DEVELOPING PRODUCTS FOR TREATMENT

Docket No. 00D-1318, CDER 9952

Submitted to

Dockets Management Branch (HFA-305), FDA

by

The Purdue Frederick Company
Stamford, CT

August 25, 2000

This communication is in response to the solicitation of comments for the draft guidance of June 28, 2000: Chronic Cutaneous Ulcer And Burn Wounds - Developing Products For Treatment (Docket No. 00D-1318). We have carefully reviewed this draft guidance and in general find it an excellent set of recommendations.

As the manufacturer of wound care products containing the topical antiseptic povidone iodine (PVP-I), we believe that these guidelines should be broadly applicable to all developmental ulcer and burn care treatments. Several topical antiseptics, including PVP-I as well as other chemically distinct solutions, are commonly used in the management of these types of skin infections in clinical practice. For example, the Betadine® brand of PVP-I is considered a "standard of therapy" by CDER as adjunctive therapy for treatment of complicated skin and skin structure infections (FDA, Draft Guidance for Industry: Uncomplicated and Complicated Skin and Skin Structure Infections – Developing Antimicrobial Drugs for Treatment, July 1998, p. 9).

We suggest two additions and/or modifications to the draft document that would broaden the practical utility of this industry guidance to better include the use of topical antiseptics. These suggestions are based on the broad recognition that topical antiseptics exhibit potent antimicrobial activities to help prevent infections and allow healing processes to proceed. Existing text from the draft document is italicized, and our recommended new text is in Bold.

Comment 1

II. CLAIMS

C. Other Considerations Related to Improved Wound Care

1. Wound Infection Control, page 4, end of second sentence:

Infected wounds do not heal, and the primary efficacy outcome for topical anti-infective wound products can be either healing or control of infection. Both outcomes should be assessed, and reasonable concordance would be expected. A secondary efficacy outcome can be avoidance of the use of systemic antibiotics when the anti-infective is a chemical antiseptic (e.g., PVP-I). Products for treatment or prophylaxis of infection...

Rationale: In chronic wounds, topical antiseptics play a role in controlling bacterial proliferation in damaged tissue that is susceptible to development of infection. Once colonization has been transformed into infection it is often necessary to treat with systemic antibiotics. Antiseptics such as PVP-I help prevent the development of infection and may therefore avoid the use of systemic antibiotics. It is clear from the growing epidemic of antimicrobial resistance among bacteria, particularly in the hospital and nursing home setting, that avoidance of antibiotic use is a positive outcome both for the individual patient being treated (to avoid development of difficult-to-treat infections) and from a public health perspective. The July 1998 FDA Draft Guidance Document "Uncomplicated and Complicated Skin and Skin Structure Infections – Developing Antimicrobial Drugs for Treatment" specifically requires antimicrobial susceptibility testing ("in an age where resistance development is not uncommon") in the event of a response failure, thus emphasizing the problem of emerging antimicrobial resistance (p. 14 of 1998 Draft Guidance).

Comment 2

IV. CLINICAL TRIAL CONSIDERATIONS

E. Standard Care

1. Standard Care Considerations for Chronic Cutaneous Ulcers

d. Infection Control, page 13, Third sentence:

*Acceptable ulcers for enrollment can often be achieved during a run-in period with thorough debridement and other **standards of therapy (e.g. topical solutions including antimicrobial agents such as Betadine).** A high incidence of true infection...*

Rationale: Topical antiseptics, including the use of PVP-I, is extremely common in the setting of ulcer care. Health care providers make every effort to avoid the occurrence of frank infection and wound sepsis since the underlying ulcer pathology often makes such infections extremely difficult to eradicate. Many health care personnel involved in studies for ulcer care routinely use agents such as PVP-I for infection control and will not wish to place their patients at increased risk by avoiding the use of antiseptics as prophylactic treatment. CDER has recognized Betadine® form of PVP-I as a “standard of therapy” for uncomplicated and complicated skin and skin structure infections, warned that disqualification of patients given such adjunctive therapy could “lead to major enrollment problems”, and recommended that such adjunctive therapies be allowed and controlled for by appropriate blinding and randomization (FDA, Draft Guidance for Industry: Uncomplicated and Complicated Skin and Skin Structure Infections – Developing Antimicrobial Drugs for Treatment, July 1998, p. 9).

We appreciate the opportunity to have submitted these comments. Our suggestions have been developed such that the guidelines might be expanded to better include the use of existing and experimental topical antiseptics, and be more consistent with messages stressed by the earlier FDA draft guidance document on developing antimicrobial drugs for skin infections (Uncomplicated and Complicated Skin and Skin Structure Infections – Developing Antimicrobial Drugs for Treatment, July 1998).

The Purdue Frederick Company

By:



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Medical Director, Medical Affairs

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