

September 7, 2004

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

RE: Prohibited Cattle Materials-Docket No. 2004N-0081

As manufacturers of patented wound care products derived solely from hydrolyzed collagen, the new regulations would severely impact the well being and healthcare of potentially millions of users; both OTC and medical practitioners. For example, our products have recently been awarded full approval at all veterans hospitals and similar government institutions.

We are The Hymed Group Corporation, 1890 Bucknell Drive, Bethlehem, PA 18015, holders of 510K's relative to the use of wound care fillers and topical dressings.

The processing used to manufacture hydrolyzed collagen, i.e. processing during hydrolysis, has been shown to clearly mitigate any potential spread of BSE. Further, the use of bovine hides as a raw material for the production has been shown to carry no risk of BSE.

Further to processing, our powder materials are gamma radiated to attain sterility.

We realize that the interim rule applies only to human food and cosmetics, but please understand that this rule will affect the supply of hydrolyzed collagen and, will, in our opinion, be unduly inappropriate and damaging to the medical industry.

In conclusion, bovine hides are the principal source of hydrolyzed collagen. As such, the manufacturing processes that are employed nullify any exposure to BSE. Further, as a manufacturer of product under a 510K FDA clearance for marketing, we maintain all records under cGMP (current good manufacturing practice) and are audited by the FDA. We further believe that before the FDA implements rules of this type, manufacturing processes and end-use benefits should be examined and weighed against potential risks. In this case, no risk is at hand.

We ask that the new rules be examined and reviewed thoroughly and not include medical use of hydrolyzed collagen. We would greatly appreciate your support in this matter.

Sincerely,

Dr. George D. Petito
President