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August 29, 2007

Division of Dockets Management (HFA-305),
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD

Re: Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document:
Tissue Adhesive for the Topical Approximation of Skin, Docket No. 2007D-0234

I have reviewed the draft guidance document issued on July 3, 2007. The draft is well written. Declassification is welcomed and appropriate given the long history of safety that cyanoacrylate adhesives have exhibited when used topically for laceration and incision closure.

In the guidance, I am particularly glad the FDA plans to essentially waive the need for clinical trials when trying to prove that a new adhesive is similar to an existing predicate. Having performed many clinical trials, animal tests and bench testing on these materials I firmly believe the best measure to prove similarity is through physical performance testing (bench or animal), biocompatibility and analytical testing in a controlled environment. There are just too many uncontrolled variables in a clinical trial; patient and wound factors vary greatly and are difficult to control, except in a costly large randomized clinical trial (RCT). Even when done these trials still often give inconclusive data on rare events like infection and dehiscence. It is much more efficient and appropriate to test these adhesives in a controlled setting. I believe most of this can be accomplished using bench testing without sacrificing animals.

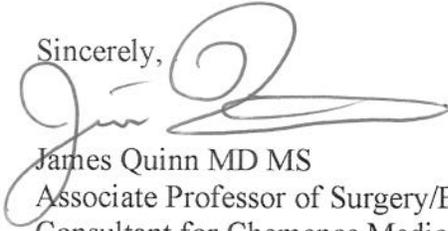
To date the FDA has approved butyl, 2-octyl and combinations of these cyanoacrylates for topical skin adhesives. Butyl CA has the longest history while Octyl CA has demonstrated a more useful set of clinical properties and a safe toxicity profile. It is likely that other cyanoacrylates with different alkyl groups may have other physical properties making them even more advantageous for physicians and patients. It is well known that changes to the alkyl side chain can greatly effect the physical properties and toxicity of cyanoacrylate adhesives.

It is unclear from the guidance document if the FDA will allow new adhesives to claim octyl, butyl or blends of these as predicate devices. In my opinion, given they are in the same class of materials, they should be considered under the special controls in this document using the "approved for use" cyanoacrylates as predicates as long as they pass established biocompatibility standards, physical testing (where they perform at least as well as predicates), are sterile and meet the same manufacturing and analytical standards as the existing predicate devices. Essentially while they may not be specifically an octyl,

butyl or combination, the approval of these adhesives should meet the same high standards set forth in the draft document and not necessitate the need for clinical trials. This will provide newer safe innovative products and technology using the least burdensome approach for the safe topical use of cyanoacrylate adhesives.

Perhaps the FDA is already planning this approach, however, I thought this point to be unclear in the draft. I further recommend the point be clarified that the guidance applies to all topical cyanoacrylates that can pass the rigorous controls outlined in the draft document.

Sincerely,

A handwritten signature in black ink, appearing to read 'Jim Quinn', with a large, stylized flourish extending to the right.

James Quinn MD MS
Associate Professor of Surgery/Emergency Medicine
Consultant for Chemence Medical Products Inc.