Colorcon
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October 31, 2003

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

RE: Docket No. 2003N-0361
Anti-counterfeiting Drug Initiative

Colorcon would like to submit additional comments to the docket concerning our 5D-ID Tablet Authentication Technology for Counterfeit Protection and Reduction of Medication errors. A detailed document which describes the technology and how it could be used in the Anti-counterfeiting Drug Initiative is attached.

Most of the technologies being considered as anti-counterfeiting measures are related to various types of packaging solutions. We believe that it is critical that drug products also have anti-counterfeiting measures incorporated directly into the tablets themselves since drug tablets can be removed during the distribution cycle of these drugs for various reasons, some legitimate, some illegitimate. The On-Tablet solutions which we have developed, along with our partners, provide anti-counterfeiting measures that are very difficult to fake and make the tablets easy to identify by appropriate parties including the patients themselves which is where the highest level of counterfeit protection needs to be.

Please review the attached document to gain a good understanding of the basic technology we have developed. Further details can be shared with the Counterfeit Task Force and the agency confidentially at a later date. Some of this information has already been submitted directly to the Task Force and discussed at the recent FDA Public Meeting in Washington on October 15, 2003.

Colorcon would be interested in participating in a meeting with FDA to further discuss the potential for this technology to provide anti-counterfeiting protection, reduce medication errors and improve patient safety. Please let me know when we could possibly set up a meeting. My telephone number is 215-661-2513.

Thank you for the opportunity to comment on your proposed regulation.

Very Truly Yours,

David R. Schoneker
Director of Global Regulatory Affairs

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