@KB@M#D@BJ@FHMF#

Alcan Packaging Kreuzlingen AG

Finkernstrasse 34
CH-8280 Kreuzlingen
Switzerland
#

Tel.: +41 71 677 71 11
Fax: +41 71 677 73 33
www.alcan.com

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

March 8, 2006

Docket No. 2005N-0510 – FDA Anti-Counterfeit Drug Initiative Public Workshop

Dear Sir or Madam:

In contrast to the many innovative and progressive patient care developments, the health & welfare of patients around the world also faces serious challenges, including:

1. the growing presence of counterfeit drugs in established supply chains
2. the unacceptable number of medical errors that account for a high number of deaths annually and billions of $ in additional hospital costs
3. low patient compliance, which jeopardize the intended patient recovery and leads to rehospitalization and higher healthcare costs.

These issues highlight specific and differentiated need areas:

1. Pharmaceutical product security
2. Pharmaceutical supply chain integrity
3. Pharmaceutical compliance

Alcan Global Pharmaceutical Packaging supports the consumer health and safety enhancing activities of the FDA, the pharmaceutical industry and the host of technology providers, via the provision of solutions that address the need areas noted above.

Specifically, we applaud the identification of the four technology pillars as noted in the FDA's February 2004 Report "Combating Counterfeit Drugs":

1. Unit of use packaging
2. Tamper evident packaging
3. Authentication technology
4. RFID technology

We believe, however that these technologies can be employed to address multiple need areas, therefore requiring a clear definition of the "jobs to be done" and a differentiated approach towards implementation.

Pharmaceutical Product Security & Packaging

Authentication tools are being employed today on unit of use packaging that are helping to address the growing volume of counterfeit drugs that reach the consumer via both regulated pharmaceutical supply chains and currently unregulated express mail routes. **The closer one can employ anti-counterfeit solutions to the product, the inherently safer the solution.**

These tools can be provided in overt, covert and forensic forms. The burgeoning number of innovative solutions attests to the creative forces unleashed in the industry. These creative alternatives have developed in part because FDA has not chosen one technology. **We believe that it is critical to continue to encourage innovative solutions by not specifying one enabling technology.**

In terms of product security, the FDA has strongly supported the development of RFID. RFID technology, provided it is adopted by the entire supply chain, represents the best potential means of achieving a fully compliant Electronic Product Code (EPC).
At this stage, however, until standards can be agreed, encryption technology improved and costs reduced, **we believe the technology can not be taken seriously in addressing security needs.**

In the recent FDA workshop it was clear that there was confusion over what number should be used to identify or serialize the package. The Pharmacies wanted the NDC number included, the brand owners did not. The EPC global number was suggested, but this number can be predicted and counterfeited. The only number that would be secure in an RFID system is a random number. This random number can then be connected to a data base that contains all of the other numbers that are important to all levels of the supply chain. Once the leap is made to a random number there are cost effective alternative solutions to RFID

There are alternative serialization solutions that also include pass / fail authentication capabilities. These products come at a much lower cost than RFID, and could represent a phased introduction of an EPC into the supply chain. They rely on biometric scans of the product. Some use taggants and some do not. Alcan Packaging is trialing several of these technologies and introducing them to pharmaceutical customers. The support for such solutions is growing in the market! These solutions will work very well at the item level for authentication. They could be combined with RFID technology at the case and pallet level to provide a tracking and tracing and inventory management system.

Printed electronic are also advancing. The ability to print a chipless circuit is almost ready. This technology could be used today to encode a random number on the package. The random number can be scanned and linked to the NDC and EPC numbers for the product. The beauty of the random number is the small amount of capacity it requires vs the 96 bits for the EPC Global number. The privacy issues are also eliminated with a random number.

Pharmaceutical Supply Chain

RFID offers valuable logistics and inventory management capabilities. These can certainly be applied to the pharmaceutical supply chain. Even more important, it seems, is the supply chain security these capabilities offer. RFID technology makes economic sense at the case and pallet level. If item level identification is provided by a different technology it also eliminates the issues with frequency choice for RFID.

Pharmaceutical Compliance

Improving patient compliance is increasingly recognized as a necessary step in improving patient health and reducing overall health costs. Inexpensive item level identification technologies could be linked to compliance systems. Their low cost would help to encourage their widespread use. Legislating RFID technology would slow down the development of these low cost alternatives and limit the application. It is our belief that improving compliance could significantly improve the quality of life for many patients. This category will benefit from the variety of innovative technology options that are under development in the anti-counterfeiting arena. We encourage FDA to continue to highlight the problems, and focus industry attention on the solutions.

Sincerely,

Scott M. Denley
Global Product Manager

Tel direct: +41 71 677 7244
Fax direct: +41 71 677 7333
e-mail: scott.denley@alcan.com