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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

May 12, 2008

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

RE: RESPONSE OF THE CALIFORNIA STATE BOARD OF PHARMACY
Docket No. FDA-2008-N-0121
Technologies for Prescription Drug Identification, Validation, Track and Trace, or Authentication; Request for Information

To Whom It May Concern:

I write on behalf of the California State Board of Pharmacy. We are pleased to have this opportunity to respond to a Request for Information included in Docket No. FDA-2008-N-0121, which has been titled "Technologies for Prescription Drug Identification, Validation, Track and Trace, or Authentication; Request for Information." We are encouraged by the timely request for information and support expeditious action by the FDA in this vital standards-setting endeavor.

Our Historical Perspective in California

As you may know, the Board is the agency within California primarily responsible for the enforcement of California's drug pedigree law, a mandated serialization, electronic pedigree, and track and trace system designed to enhance the security of the drug supply chain. The California pedigree law was first enacted in 2004, with an initial effective date of January 1, 2007, and then modified and extended in 2006 by additional legislation that pushed the effective date to January 1, 2009. Recently, the Board exercised authority delegated to it by the 2006 legislation to further extend the effective date for implementation of the pedigree requirements to January 1, 2011.

The Board and its staff thus have several years experience developing and implementing pedigree laws. Further, since 2005 the Board and its staff have engaged in extensive outreach to all segments of the drug supply chain on the California pedigree law. Over that time, the Board has been grateful to receive invaluable support from the FDA in those efforts, and for its law.

This FDA support for California's pedigree law has mirrored a historical commitment at the FDA, as expressed for example in the 2004 and 2006 Reports by the FDA's Counterfeit Drug Task Force, to the same principles captured in California's pedigree law: a drug supply chain in which security is enhanced by a *universal* electronic pedigree requirement with full-system track and trace, and mass serialization *at the unit level* with standardized unique numerical identifiers. Both the FDA and California prefer, and assume this system will utilize, RFID technology.

The development of industry standards to accomplish an interoperable infrastructure is a necessary step in the implementation of any pedigree requirement. Standards for a standardized numerical identifier and for a technology or technologies to carry these identifiers (data carriers) are especially crucial. We therefore welcome and are enthusiastic about the FDA's efforts.

Response to Request for Information

The Board has also been pleased to observe over the last several years that much if not all of the baseline work that would be required for development and implementation of national and international consensus industry standards has already been accomplished, at least in part during the industry's response to the imposition of the California and Florida pedigree requirements. As you are no doubt aware, nearly all of that effort has been conducted by or under the guidance and with the assistance of GS1 and/or GS1 US and/or EPCglobal Inc., the various incarnations of the centralized, national and international, neutral, and non-profit, standards-setting organization.

We expect and assume that GS1/EPCglobal will submit its own response(s), and will not attempt to provide the level of detail and specificity we assume will be provided therein. Instead, we will limit our comments to some basic principles and preferences we have developed over the last several years based on the vast quantity and variety of information we have collected.

1. Relevant Available Technologies

We will assume that the call for information on "promising technologies" for prescription drug identification, validation, track and trace, or authentication is primarily or exclusively a call for comments on the appropriate data carrier(s) to be affixed to drug product packaging to carry the unique numerical identifier at the product/unit level necessary to a universal e-pedigree, mass serialization, track and trace system. This seems to have been the focus of the 2007 FDAAA.

We are unfamiliar with any encryption technology or nanotechnology applicable to this task. Every industry participant, technology vendor, or other source of information from whom we have heard over the last several years has identified two possible technologies to be used in isolation or together for this task: 2D (Data Matrix) Barcodes, and RFID (EPC) tags.

Of the two, it is clear to the Board from all of the evidence that it has received that RFID is a vastly superior technology for all of the purposes served by an electronic pedigree/track and trace system, and should be the industry standard for data carriers. 2D Barcodes have utility as a temporary or interim solution, and as a back-up technology on packaging in the event of a (rare) RFID tag failure. However, in the long term, 2D Barcodes should not be a primary technology, and should be used solely as a secondary or back-up technology to the primary RFID tag(s).

This is particularly true for individual unit packaging, but the Board also believes that the benefits of RFID technology are at least as demonstrable at the case or pallet level.

2. Strengths and Limitations, Costs, Benefits, Feasibility, Utility

The advantages of RFID technology, both in its own right and by comparison to available 2D Barcodes, are legion. Indeed, the only advantage that RFID does *not* have over 2D Barcodes is cost of implementation, which is presently higher. But RFID costs have plummeted recently, and will fall farther. Moreover, the costs of RFID are substantially outweighed by its benefits.

Among other benefits, RFID tags are less easily counterfeited or duplicated than are other data carriers, including 2D Barcodes. This is true not only because the technology itself is not as easily replicated as, e.g., a printable 2D Barcode, but also because RFID (EPC) tags are typically given a unique identifier (e.g., Tag ID) by the tag manufacturer that confirms its authenticity, an additional level of security from widespread duplication or counterfeiting.

Perhaps most importantly, RFID is a non-line-of-sight technology, permitting the reading of unit-, case- and pallet-level tags without being able to see the tags, also from varying distances and/or through several layers of packaging. RFID is therefore the *only* available technology that will permit mass serialization and item-level track and trace of drug products throughout the U.S. supply chain *without* requiring either: a significant disruption of present practices and a dramatic increase in processing times due to the opening of every case or container; or inference on such a large scale that mass serialization/item-level tracking mandates lose much of their salience. It is largely this capacity of RFID that led to the assumption both by the FDA and California that any pharmaceutical pedigree/track and trace system would rely on an RFID-based infrastructure. By contrast, the line of sight (and immediate proximity) required to read a 2D Barcode makes it a far less optimum technology to support current supply chain requirements and efficiencies.

A related but also separable advantage of RFID tags over 2D Barcodes is that systems for reading RFID tags are capable of reading multiple tags at one time, while each 2D Barcode must be individually read by a camera-based reader. This builds bottlenecks into any system based on 2D Barcode technology, and reduces possible efficiencies. The possible return on investment for an implementation of RFID therefore also has a far greater upside than it does for 2D Barcode.

RFID tags and technology also have other advantages over other technologies, including 2D Barcode, among them: the extensibility of RFID (EPC) tags for optimizing capabilities, such as by adding extra data to the tag, adding sensors for temperature, pressure, light, the distinctions between “active” (smart) and “passive” (dumb) tags, and so forth; and the variety of frequencies, read ranges and sizes in which RFID tags are already available, not to mention the possibility of further developments in tag size and placement. There are already multiple options in the market for incorporating RFID tags into or under labels, and/or into or under packaging materials; these options are not available for 2D Barcode technology, which requires the visible, printed, marker. These examples and others not mentioned here illustrate the greater flexibility of RFID tags and technology, not to mention its ability to free up label space for other purposes.

The strength of RFID technology for supply chain security and visibility is reflected in its widespread and growing adoption in a number of industries. For example: the U.S. Department of Defense has set guidelines, requirements, and deadlines for RFID tagging (and tracking) of its contractor-supplied defense materiel on pallets, cases, and individual high-value items; Wal-Mart has for several years encouraged suppliers’ use of RFID tagging; and Sam’s Club announced this year an initiative to require supplier individual-item RFID tagging by 2010. Other industries are also making widespread use of RFID tagging on individual items, including on DVDs, items of clothing, and other mass-produced retail items. A growing number of public and private library systems also use RFID technology to automate and expedite item tracking and visibility.

3. Interoperability

Interoperability is ensured by committing to a standards-based technology environment. With regard to RFID (and 2D Barcode) technology, this environment is already in place.

4. Necessary Standards

It appears that all of the standards necessary to full implementation of RFID technology in the pharmaceutical supply chain have already been developed and implemented or are in the final stages of development and implementation. The GS1/EPCglobal system/suite of standards is fully comprehensive, including standardized identifiers, attributes, and data carriers.

With regard to RFID technology specifically, GS1/EPCglobal has ratified the necessary data carrier and tag data standards. For example, GS1/EPCglobal has at least seven standards in place that relate to RFID (EPC) tags and readers, perhaps most prominent among these its EPC UHF Tag (Class 1 Gen 2) standard for "Gen 2" RFID UHF tags. GS1/EPCglobal expects full ratification and approval of its EPC HF Tag (Class 1 Gen 2) – for "Gen 2" RFID HF tags – at or before the end of calendar year 2008. The comprehensive suite of standards agreed to under the aegis of GS1/EPCglobal has permitted innumerable vendors to operate in this space, to supply a technology that is open and standards-based, and therefore interoperable with other vendors.

The only obvious remaining piece with regard to RFID technology and/or standards is the speculation about whether RFID technology or the fields generated thereby might have an effect on the stability, potency, efficacy, etc. of biologics, particularly large proteins. To date, all of the available data of which the Board is aware suggests there is no such effect, and the Board has not been made aware of any studies or data demonstrating any such effect. However, the FDA might wish to establish guidelines or standards for such data collection, or for application to biologics if the FDA determines that further testing is necessary to demonstrate this lack of effect.

The Board looks forward to continuing its historical cooperation with the FDA as it sets forth on this standards-setting endeavor. The Board is very hopeful that the FDA can move very quickly to establish these national standards, as the FDA has indicated is its intent by moving to expeditiously publish the pertinent Docket event(s) and request(s) for comments/information.

Thank you for your attention to these matters, and for your willingness to hear our input. We look forward to continuing to work together to secure the nation's drug supply. Please feel free to contact the Board at any time if we can be of assistance. The best route for contact is via Executive Officer Virginia Herold, at (916) 574-7911, or Virginia_Herold@dca.ca.gov.

Sincerely,

WILLIAM POWERS
President, California State Board of Pharmacy