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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-0120**  
*Standards for Standardized Numerical Identifier, Validation, Track and Trace, and Authentication for Prescription Drugs; Request for Comments*

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 the Request for Comments included in Docket No. FDA-2008-N-0120, which has been titled "Standards for Standardized Numerical Identifier, Validation, Track and Trace, and Authentication for Prescription Drugs; Request for Comments." We are encouraged by 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 Comments

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.

#### **A. Standard Numerical Identifier**

Under the aegis of GS1/EPCglobal, the industry has already completed all or nearly all of the necessary work on development and implementation of a standardized numerical identifier to be used to identify individual products (and cases and pallets) in the supply chain. The standard identifier already in use within the industry is the Global Trade Item Number (GTIN), developed by GS1/EPCglobal. The Board is not aware of any competing or alternative standard identifier.

The Board strongly encourages the FDA to adopt the GS1/EPCglobal standard identifier. The GTIN is already in use and approved by the FDA for marking pharmaceutical products via a linear bar code. It has utility and extensibility for use with all other data carriers, as well. It is in use on packaging already with a significant majority of U.S. drug manufacturers and distributors.

We will not respond individually to all of the sub-categories or questions included in this sub-part (A), as standards-setting organization(s), industry participants, and technology vendors are better able to do so. We will be generally satisfied with urging adoption of the GTIN, except to note a few comments responsive to the specific questions posed in the notice:

- With regard to whether the standard numerical identifier should contain recognizable characteristics such as the National Drug Code (NDC) Directory number as part of its sequence or should be purely random, we note that the GTIN has the capacity to, and presently does, include/incorporate the NDC number. Though we recognize that this may reduce the full interchangeability of GTINs internationally due to inclusion of a U.S.-only NDC number, several of the professional pharmacist members of the Board have expressed a preference for inclusion of an NDC number in standard identifier(s). So much of the present tracking, billing, and payment infrastructure in the U.S. uses NDC number as a reference point that a certain level of comfort has developed with use of this identifier, and failure to include the NDC number may cause confusion.

- With regard to whether the standard numerical identifier should be in more than one place (e.g., at both the package and pallet level), we believe that full track and trace/pedigree capacity will require application of unique identifiers on *both* the individual item-level package *and* the case, pallet, or other aggregation. What is most crucial is that individual item-level (mass) serialization and application of unique identifiers be mandated by law; the application of identifiers to cases and pallets naturally follows.
- With regard to machine-readable versus human-readable, we feel strongly that it is of crucial importance to have machine-readable identifiers. Automatic data capture is an absolute necessity to preserve and extend the current processes and efficiencies in the drug supply chain. The fewer allowances that are made for human error the better. In fact, we also believe it critical to mandate or at least strongly encourage that standard numerical identifiers be encoded on carriers capable of non-line-of-sight data capture. This is the only means of transmission that is feasible for the entire supply chain.
- With regard to other questions posed under the “Characteristics” heading, we limit our comments to the observation that, as you have obviously realized, these are the kinds of decisions that must be made by industry consensus. In our view, there must be standards regarding whether or not to include a product type header/digit, how the parties in the supply chain ensure that numbers are unique and not duplicated, and/or whether or not the standard numerical identifier includes lot or batch number. What the particular decisions are with regard to those questions are of less concern to us.
- As for the “Standards” questions, we simply repeat our recommendation that the FDA strongly consider adoption of the GTIN as the pharmaceutical industry standard. The GTIN already enjoys that status within the industry, enjoying widespread adoption in the U.S. and internationally. There is no need to re-create this development process. We particularly encourage adoption of the SGTIN-96, which is the version applicable to serialization of drug products using RFID tag technology as the data carrier.
- And finally, with regard to the “Economic Impact” and/or “Harmonization with Other Countries” questions, we will again largely leave those to others to answer. However, we do observe that the economic impact(s) of universal item-level (mass) application of standard numerical identifiers, whatever they might be, are more than balanced by the dramatic impact on public health and safety this technology standard promises. A secure supply chain depends on an ability to reliably track and trace drug products, to prevent infiltration of counterfeit, misbranded, and/or adulterated products. And as is evidenced by the recent experience with Heparin, an effective recall also depends on a serialized-to-the-unit-level drug supply, that is absent now. Unit-level serialization will also bring the U.S. supply chain *more* in line with international standards, as it is much more the practice in other countries to have patient-level serialization (as well as packaging). It is high time that the U.S. employed a similar practice standard.

## **B. Standards for Validation**

We are not sure what is meant by use of the terms “Standards for Validation.” This is not a terminology we are accustomed to hearing, nor does it appear to clearly relate to any particular standard(s) or industry practice(s) we have encountered over the last several years.

To our knowledge, no such particular, specific “standards” for “validation of prescription drugs” presently exist, aside from those standards, practices and procedures developed to ensure and enable compliance with legal requirements such as those mandated in California and Florida, like the GS1/EPCglobal Pedigree and EPCIS standards. These standards *include* provisions and allowances for validations of prescription drugs, but would probably not be said to *be* such.

### **C. Standards for Track and Trace**

Likewise, we are not sure what is meant by “Standards for Track and Trace.” This is not a terminology we are accustomed to hearing, nor does it appear to clearly relate to any particular standard(s) or industry practice(s) we have encountered over the last several years.

Again, to our knowledge, no such particular, specific “standards” for “track and trace of products in the supply chain, generally” presently exist, aside from those standards, practices and procedures developed to ensure and enable compliance with legal requirements such as those set by California and Florida, like the GS1/EPCglobal Pedigree and EPCIS standards. Each of these standards *include* provisions and allowances for, or *enable*, tracking and tracing of drugs.

### **D. Standards for Authentication**

And finally, we are also not sure what is meant by “Standards for Authentication.” This is also not a terminology we are accustomed to hearing, nor does it appear to clearly relate to any particular standard(s) or industry practice(s) we have encountered over the last several years.

Again, to our knowledge, no such particular, specific “standards” for “authentication of products in the supply chain, generally” presently exist, aside from those standards, practices and procedures developed to ensure and enable compliance with legal requirements such as those set by California and Florida, like the GS1/EPCglobal Pedigree and EPCIS standards. Each of these standards *include* provisions and allowances for, or *enable*, authentication of drug products.

### **E. Prioritization**

What is clear to us, and requires no clarification, is that the highest priorities for the FDA, in this invaluable standards-setting venture, ought to be *immediate* and *concurrent* development of two standards: (1) the specification(s) for the standard numerical identifier to be placed on the item-level (and case- or pallet-level) packaging for prescription drugs; and (2) the standard(s) for the data carrier(s) that should be used to encode and affix those numerical identifiers.

As we have stated in our separate submission in response to the accompanying Docket on the specific subject of promising technologies, we believe it is imperative that the FDA settle on RFID tags and technology as the mandated/preferred carrier. To do so, we hope the FDA takes a leadership role in also settling the question of propriety of use of RFID tags on biologic products.

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](mailto:Virginia_Herold@dca.ca.gov).

Sincerely,

A handwritten signature in cursive script that reads "William Powers".

WILLIAM POWERS  
President, California State Board of Pharmacy