

## FOR IMMEDIATE RELEASE

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## AS FDA GUIDELINE CALLS FOR MORE SECURE PHARMACEUTICAL SUPPLY CHAIN, COVECTRA OFFERS ROBUST SOLUTIONS

### Official FDA Guidance Document Includes Standardized Numerical Identification (SNI) on Prescription Packaging to Combat Counterfeiting

**SOUTHBOROUGH, MA - April 13, 2010** – COVECTRA, a multi-layered brand protection solutions provider offering [serialization, authentication, and track and trace technology services](#), announces the availability of easy-to-implement technology solutions to support pharmaceutical companies in quickly responding to an FDA guideline issued last week, for regulatory standards in developing a secure pharmaceutical supply chain. In addition to offering affordable solutions for FDA's suggested guidance that all pharmaceutical companies print SNI (Standardized Numerical Identification) codes on all secondary packaging, COVECTRA uniquely provides unit dose identification technology that further secures prescription drugs and medical devices traveling through the complex supply chain to consumers, making each pill or medical device verifiable as an authentic product.

In an effort to contribute to anti-counterfeiting initiatives in the United States, as the first of several guidances and regulations that the FDA plans to issue and implement, the [“Standards for Securing the Drug Supply Chain – Standardized Numerical Identification \(SNI\) for Prescription Drug Packages”](#) document indicates that standards must be developed for identification, validation, authentication, and tracking and tracing of prescription drugs. It also recommends that an SNI be applied to a prescription drug at the point of manufacturing and repackaging, at the package or pallet level. This SNI, which should be applied to each new package in both human-readable and machine-readable forms, will be linked back to the manufacturer's SNI for the container. In this document, the FDA recommends specifically that the SNI for most prescription drug packages should be a serialized National Drug Code (sNDC) that corresponds to the specific drug product combined with a unique serial number, generated by the manufacturer or re-packer for each individual package, which should have no more than 20 characters.

#### Example of a serialized National Drug Code (sNDC)

##### NDC

55555 666 77

labeler code + product code + package code

+

##### SERIAL NUMBER

11111111111111111111

unique, up to 20 characters

## COVECTRA OFFERS SOLUTION TO COMPLY WITH FDA GUIDANCE/ Pg. 2

COVECTRA offers pharmaceutical manufacturers the technology to support these newly identified standards, while also providing the ability to apply even more significant security and integrity measures which uniquely allow traceability down to the unit and dosage level. COVECTRA's security offerings are applied in layers, from simple labels and cartons with proprietary taggants, to sophisticated web-based serialization solutions that provide the brand with "end-to-end" knowledge of the product's life history and disposition. By combining these various layers of security, a product travels from manufacturing, through packaging, into distribution through multiple wholesalers, to the retailer's point of sale, and into the hands of the consumer with maximum traceability, safety and integrity.

"With up to 90% of Internet drug sites selling adulterated drugs, diversion control and counterfeiting are concerns that substantially impact the pharma industry," stated COVECTRA President and CEO, Steve Wood. "With applications providing the opportunity for traceability throughout the supply chain, manufacturers, customs officials and law enforcement can identify counterfeit and diverted product and detect how and where the product entered the supply chain," stated COVECTRA President and CEO, Steve Wood."

The COVECTRA methodology creates a sophisticated, streamlined capability to identify and prevent product diversion and counterfeiting, which, coupled with its [AuthentiTrack™ software platform](#), provides a complete portfolio of software and packaging security solutions to protect as well as enhance consumer loyalty to any valuable brand. Additionally, the companies' unique smartphone application can be used to input serialized human readable codes that are unique to a unit package. Once the code is entered into the smartphone, the application checks it against COVECTRA's AuthentiTrack™ software platform which can be used to track the product through all levels of distribution from the point of packaging throughout the supply chain, and ultimately to the consumer. The consumer is then able to verify authenticity, communicate directly with the manufacturer, and enroll in product promotions programs.

### About COVECTRA

Uniquely, COVECTRA provides solutions from unit package authentication and verification to serialization of all levels of packaging. COVECTRA's products include security labels with overt and covert security feature serialization, authentication and track-and-trace software applications. COVECTRA also provides professional services to assist clients with brand protection strategies, security label designs, and printing and packaging material and equipment specification. In cooperation with its [strategic partner, MSO Group, Ltd](#), of Belfast, Ireland, a manufacturer of specialty, high quality labels and cartons, COVECTRA provides technology that simultaneously secures integrity, brand imaging and brand loyalty for prescription drugs, medical devices, and luxury products.