CDEX Inc.
The Technology Development Company

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Division of Docket Management (HFA-305)
Food and Drug Administration
5630 Fisher's Lane
Room 1061
Rockville, Maryland 20852

To the FDA Counterfeit Drug Task Force:

In response to verbal requests made by Members of the FDA's Counterfeit Drug Task Force during the October 15, 2003 Anti-Counterfeiting Public Meeting, CDEX Inc. ("CDEX") offers the following comments to the Interim Report[1]. We thank the FDA for the opportunity to submit comments to the Counterfeit Drug Task Force Interim Report, and offer comments directed to statements found in two areas:

- Section II.E.(1): Background Technology Issues, Types of Anti-Counterfeiting Technologies; and

- Section IV: Questions Related to the Potential Options for Improving Prescription Drug Security, Paragraph 4: What anti-counterfeiting technologies are currently being used?

CDEX supports the FDA's approach for a multi-pronged strategy to reduce points of vulnerability in our Nation's drug distribution system, and the criticality of the continuous evolution of technologies and their application to thwart criminal activities. CDEX strongly agrees that authentication and track/trace technologies are complementary, and respectfully offers these comments as a means to augment the technology at the Task Force's disposal to fulfill Commissioner McClellan's Fundamental Goals.

We wish to draw the Task Force's attention to the area of authentication technology that was otherwise not widely addressed in Section II.E.(1) of the survey of available types of anti-counterfeiting technologies, and is a clear extension to the FDA's definition of a Forensic Authentication Technology. We request that the FDA update the definition of "Forensic Technologies" to include those solutions that use signatures of constituent chemical ingredients, and further, to recognize that these technologies are currently being used as an effective first line of defense against counterfeit medications.

[1] CDEX Inc. is a technology development company with corporate offices in Rockville, Maryland, and a research and development facility in Tucson, Arizona. The SafeMed System technology described in these comments is based on CDEX's extensive research and development activities related to chemical detection e.g. explosives, medication and illegal drugs (see testing results on the CDEX web site at www.cdex-inc.com).

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Authentication of Medication Safety by Validation and/or Identification of the Medication Itself

The report offers less than adequate description of technologies that validate medication by identifying constituent chemical ingredients and/or the active pharmaceutical ingredient of the drug itself. Such technologies allow for cost effective verification that the pill or liquid has not been counterfeited by substitution or dilution of the constituent ingredients.

The Interim Report states that "*Forensic technologies are protective measures that require sophisticated analytical equipment, usually found in a forensic chemistry lab*"[2]. We believe that this statement does not address the considerable recent technological development and deployment of technologies that go beyond chemical markers and taggants. These devices have successfully moved out of the lab and into mobile platforms, and have been placed in the hands of non-technical workers and individuals.

We wish to make the committee aware of technologies in this area, including CDEX's, and their successful application in identifying constituent chemical ingredients, as well as the newfound ability to effectively deploy this technology in the field. This combination addresses several critical aspects needed to implement a cost effective anti-counterfeit strategy:

- Consumer safety solutions that can be successfully integrated in the existing distribution process to validate medication (not simply the packaging),
- Low cost solutions that translate to minimal impact to the consumer;
- Efficiently checked imported medications for counterfeits and validated at multiple checkpoints, including points of sales, distribution and by Customs officials.

CDEX Chemical Detection Technology

Among the forensic technologies, CDEX is in the process of finalizing development on a real time non-destructive method for validating medication[3], incorporating the advantages of direct identification of medication in a user-friendly portable "point and shoot" platform.

CDEX SafeMed System products use chemical spectral signatures to provide real time identification/validation of solid and liquid medications contained in the CDEX database.

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[2] Counterfeit Drug Task Force Interim Report of October 2003; Section E. Background: Technology Issues, 1. Types of Anti-Counterfeiting Technologies.

[3] Another technology, under the auspices of the German Pharma Health Fund (GPHF) is titled Minilab®, the provision of simple test methods which enable identification of substandard or counterfeited pharmaceuticals under the specific conditions encountered in developing countries. Numerous Minilabs are currently successfully being used in Africa, Asia and Central and South America. The Minilab has also been integrated into the Roll Back Malaria Program of the World Health Organization.

This allows for verification that the medication has not been counterfeited by substitution or dilution of the constituent ingredients. Scanning the medication is non-destructive and can be done in real time.

At the October 15th FDA Public Forum, CDEX was pleased to demonstrate to several members of the Task Force a working prototype to address several critical aspects needed to implement a cost effective anti-counterfeit strategy.

Verification can be accomplished either with the stylus in direct contact with the pill or through clear bubble packaging. Liquid medication can be similarly validated while in unopened clear glass vials or pre-filled syringes.

Exhibit A: CDEX SafeMed is a portable scanning device that validates medication in real time.

The SafeMed counterfeit solution focuses on consumer safety. CDEX technology is designed to be deployed anywhere in the distribution cannel to identify counterfeit medications, including Custom's checkpoints, pharmacies, and hospitals to provide a final check before passing medications over the counter to the consumer.

Advantages of the CDEX SafeMed Solution

CDEX technology directly validates the medication by analysis of the unique composite spectra of the constituent fluoresced ingredients. CDEX technology differs from currently utilized systems which rely on "tagging" a package or pill to identify counterfeit medication only by the absence of these taggants.

CDEX SafeMed products offer several critical advantages over current techniques, as well as a wide array of potential opportunities to use the technology to maximize benefits beyond anti-counterfeiting:

- SafeMed's direct validation of the composite spectra of the medication distinguishes counterfeit "look-alike" pills and liquids not containing similar quantities of the fluoresced ingredients and binders.

- "Look-alike" packaging of counterfeit medication is defeated by chemical spectra analysis of the actual medication. This allows wholesalers, repackers, retailers, healthcare entities and pharmacists to perform final validation at time of dispensing or sale.

    - Pills can be validated through:
        - Clear bubble wrap
        - Direct physical contact

    - Liquid medications can be validated through:
        - Walls of clear glass vials and pre-filled syringes

- SafeMed's validation does not require the manufacturer or wholesalers/repackers to incorporate costly authenticating technologies into the drug product or packaging. SafeMed's advantages allow:
    - Lower cost of manufacture, packaging and distribution.
    - Minimal purchases of associated equipment and services.
    - No need for distribution-chain wide changes in infrastructure
    - Easy integration of technology into existing systems
    - Continuation of present competitive wholesale distribution practices that result in lower costs of medications to consumers.
    - Validation of drugs sourced from jurisdictions outside the FDA.
    - Customs inspection of medication at ports of entry.
    - Enforcement inspection in warehouses, transport and other sites.
    - Patients to validate their own medication by accessing this technology, which could be located in public health sites, medical clinics, or shopping malls.

The Technology

The SafeMed technology is based on CDEX's extensive research and development activities related to detection of explosives and illegal drugs (see results of testing contained on the CDEX web site at www.cdex-inc.com). The CDEX technology that supports the SafeMed System uses an ultraviolet energy source to fluoresce the medication(s). Electron decay within the medication(s) causes emission of characteristic photons that through empirically derived algorithms are used as a "fingerprint" to identify the medication(s).

To date, CDEX has previously "signatured" and built a proof of principal product that identified 38 drugs. That list of drugs can be found in the Merk Manual Seventh Edition table 301-1 "Drugs that produce serious drug interactions" (Primarily hepatic cytochrome P450 metabolic pathway drugs). A second set of approximately 330 drugs is currently being "signatured". The drugs being "signatured" include primarily pill formulations but also include liquid medication in ampoules.

CDEX is presently deploying this technology in the Personal Security Screening System (PS^3), a portable next generation trace explosive detection device. The PS^3 is designed for handheld scanning of people and their personal effects, using a wand connected via fiber optic cables to a UV source and detector, to identify presence of explosives (e.g., RDX, C4, Semtex, TATP, TNT).

Summary

We thank the FDA for the opportunity to comment on this important challenge to the health and safety of the American public. We respectfully request that the FDA update the definition of "Forensic Technologies" to include those solutions that use signatures of constituent chemical ingredients, and further, to recognize that these technologies are currently being used as an effective first line of defense against counterfeit medications. We believe inclusion of such technologies will help the Task Force achieve Commissioner McClellan's Fundamental Goals.

CDEX again thanks the Counterfeit Drug Task Force for the opportunity to provide comments to the October 15, 2003 Interim Report, and is willing to provide whatever support the Members of the Task Force may require.

Sincerely,

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