smiths

**Smiths Detection**

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

Re: Smiths Detection's Comments to Docket No. 200SN-0361 (FDA Counterfeit Drug Task Force)

To Whom It May Concern:

On behalf of Smiths Detection ("Smiths"), headquartered in Warren, New Jersey, I submit the following comments to the Food and Drug Administration's Anti-Counterfeit Drug Initiative (Docket No. 200SN-0361).

**Background: Smiths Detection**

Smiths is principally engaged in the development of analytical instruments for the rapid, high sensitivity detection of chemicals and other substances, including explosives, narcotics and chemical warfare agents. Smiths is the world leader in explosive trace detection (ETD) and has successfully deployed the IONSCAN®, an analytical instrument using Ion Mobility Spectrometry ("IMS"), for the Transportation Security Agency (TSA), the United States Armed Forces, the Federal Bureau of Investigation, the Drug Enforcement Agency, the Department of State, and the Federal Protective Service, as well as numerous foreign governments, including Israel, the United Kingdom, Canada, Argentina, Hungary, Spain, U.A.E., Italy and China. In addition to its applications in security scenarios, the IONSCAN® IMS technology is increasingly being used by pharmaceutical companies to expedite and simplify cleaning verification processes, and Smiths is exploring a range of potentially important pharmaceutical applications.

Ion Mobility Spectrometry (IMS)

IMS works by selectively ionizing organic compounds and separating them according to their unique time of flight. Solid or liquid samples are directly introduced to the analyzer by thermal desorption. Resulting vapors and selectively ionized in a controlled chemical ionization environment to produce molecular ions or molecular ion clusters.

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Ions are gated by an electronic shutter into a drift tube, colliding with neutral gas molecules at atmospheric pressure before striking the collector and generating an electric current. Ions are separated according to their size and shape based on drift time in the 3-50 msec range.

Larger ions have longer drift times than smaller ions, as a result of their large cross-sectional areas. Accurate identification is based on the detection of peaks with 0.040 msec of their expected positions.

**Smiths' IONSCAN® Technology Can Assist the FDA in its Anti-Counterfeiting Efforts**

Smiths agrees with the FDA's Counterfeit Drug Task Force Interim Report ("Report") that a multi-pronged strategy to secure the drug supply would be much more effective in protecting American consumers from the risks associated with counterfeit drugs, than would a "once-size-fits-all" approach. More importantly, as is noted in the Report, drug counterfeiters are extremely sophisticated and well organized, so the use of technology is vital to preventing and containing counterfeit drug threats.

The IONSCAN® is extremely versatile and can be programmed in many different ways to facilitate numerous scenarios, including drug-counterfeiting applications. Moreover, if properly integrated into border surveillance efforts, IONSCAN® could immediately lessen the unlawful importation of a variety of drug products. For example, the IONSCAN could be programmed to detect controlled substances unlawfully imported through Internet pharmacies, or drugs that should not be imported due to special safety and distribution restrictions (e.g., risk managed drugs, such as thalidomide, subject to FDA Import Alert #66-41). In either scenario, the accurate and proven IONSCAN® technology could be rapidly integrated into current border surveillance systems.

Furthermore, the IONSCAN® is easy to use, and is faster and less expensive than other instruments available today, with sampling typically completed within 6-20 seconds. The system's versatile software permits rapid method development, and new targets for analysis can be programmed into it within minutes. Calibration is automatic, and the IONSCAN® does not require any external gas or reactant supplies.

In conclusion, there are a number of challenges that face the FDA in developing a system to ensure that the U.S. drug supply continues to be the safest in the world. Smiths believes IMS can be an important technological component of the FDA's multi-pronged strategy.

If you have further questions regarding the application of Smiths' technologies, please do not hesitate to contact me. In addition, information on our company and technologies can be found at www.smithsdetection.com.

Sincerely,

Robert Sandor (OK)

Robert Sandor, Ph.D.
Vice President, Sales Pharma/Chemical