

# A Handheld Portable Device Based on LEDs for Use in the Detection of Counterfeit Pharmaceutical Drugs and Packaging

## Technology Summary

The FDA is seeking a device company to commercialize its patent pending handheld portable device for the detection of counterfeited pharmaceuticals. The device will be based on the technology described below. The invention was further described and claimed in provisional patent application 61/165,395 filed March 31, 2009. The FDA scientists have built highly reliable prototypes of two different models of the device and demonstrated the validity of the device for multiple applications.

A hand held portable device was designed and developed for use in the detection of counterfeit pharmaceutical products and packaging. The light source of the device emits different wavelengths of light onto a sample. The device incorporates the use of single wavelength light emitting diodes (LEDs) which generate intense single wavelengths of light. Two models of the device have been developed and manufactured. The first model incorporates only LEDs at specific wavelengths and the second model incorporates a camera and display along with the LEDs at specific wavelengths. The different LED wavelengths of light interact with the sample by either being absorbed, reflected or by generating an apparent color change in the sample. The absorption, reflection or apparent color change by the sample may be observed using different colored goggles (yellow, orange, red). The fluorescence profiles of suspect pills can be compared with the authentic article to determine legitimacy. The device can be used for field examination of suspect counterfeit pharmaceutical products, packaging and diverted pharmaceutical products. Due to its size, and the simplicity in design and use, the hand held portable LED light source can be used by health safety officials (e.g. FDA investigators), by law enforcement authorities, or by the pharmaceutical companies themselves, to rapidly screen samples for suspect counterfeit products improving the safety of that the US drug distribution chain.

## Potential Commercial Applications

- Testing for authenticity of pharmaceutical products
- Combating the ever-growing problem of counterfeiting in pharmaceutical products to protect public safety
- Traditional law enforcement activities

## Competitive Advantages

Current methods of detecting counterfeit pharmaceuticals (vibrational spectroscopy, x-ray diffraction, gas chromatography, liquid chromatography, and mass spectrometry) are expensive, bulky, and typically in a lab operated by highly trained operators.

Advantage of the LED based device include:

- Onsite testing (no lab needed)
- Small size, light and portable
- Simple to use and does not require special technical skills
- Low cost and simple to manufacture
- Reliable and provides reproducible results

**Development Stage:** Prototype

**Inventor:** Nicola Ranieri

**Intellectual Property:**

United States patent: US 9,476,839 B2, issued 10.25.2016

United States patent: US 10,101,280 B2, issued 10.16.2018

**Product Area:** Devices, Drugs

**FDA Reference:** E-2008-017

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