



FDA Facts: FDA's Counterfeit Detection Device CD-3



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Global production of FDA-regulated goods has exploded over the last decade, leading to greater numbers of suppliers, more complex multinational supply chains, and more products sourced from developing countries and emerging markets. American consumers want these products, but the increasingly global marketplace increases the risk for counterfeit, potentially dangerous goods. More than 20 million shipments arrive at our border each year and supply about 20 percent of the fresh produce, 80 percent of the seafood, 40 percent of the finished drugs, half of the medical devices and large quantities of active drug ingredients used in our country—but not all are fit to be admitted into the country.

In addition to the sheer volume of imports and foreign facilities from which those imports are sourced, there has been an increase in the variety of sources, shippers, methods of transportation, and supply-chain complexity. Because imported products are transported over increasingly complex and hard-to-track supply routes, they are vulnerable to being substituted for goods that are counterfeit or otherwise substandard, including falsified products. To ensure that the US supply chain remains one of the safest in the world, such products must be detected quickly. Innovative tools must be developed to minimize consumer exposure to unsafe products.

CD-3

Nicola Ranieri, a scientist in the FDA's Forensic Chemistry Center in Cincinnati, began exploring the use of ultraviolet light to identify counterfeit drugs. He worked first after hours at home and later joined with his colleague Mark Witkowski,



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a specialist in the science of absorption and emission of light, to design a tool that used the light of alternate wavelengths to rapidly discern differences between a product that is authentic and a potentially harmful fake.

This counterfeit detection device, CD-1, underwent two modifications that incorporated additional wavelengths, including infrared. The third generation, CD-3, completed in 2010, is suited for use not only at U.S. border crossings and international mail facilities, but also in remote areas of the developing world.

The CD-3 is a battery-operated, hand-held and inexpensive tool that costs a fraction of the price of existing laboratory-based and field-deployable technologies. It works much like a high-powered flashlight, and it can be readily used by people without scientific or technical training. Moreover, extensive tests have shown it to be effective in identifying counterfeit products and packaging.

For the last three years, CD-3 has been used at U.S. ports of entry and elsewhere by FDA investigators to check suspect products, including drugs, cosmetics, foods, medical devices and cigarettes. The gadget has successfully detected counterfeit goods, and FDA investigators found CD-3 to be helpful even in discovering product tampering and checking questionable documents.

A Potential Tool for Global Public Health Protection

For public health and other authorities around the world who work to protect the integrity of regulated products, the CD-3

has the potential to be a frontline tool for protecting patients and consumers from counterfeit or substandard goods, including medicines, strengthening the safety of the global supply chain, and hampering criminal enterprises that endanger human and animal well-being and lives. FDA hopes further testing will demonstrate the effectiveness of the CD-3 as a screening tool and encourage its wide-scale use to ensure the integrity of products that end up on the dinner table or at the bedside of patients around the world.

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