

PHARMACEUTICALS

Two New FDA Studies Cover Stable Isotopic Authentication

Two new studies conducted in cooperation with the US Food and Drug Administration found that stable isotopic fingerprints can be effective tools to identify the authenticity of pharmaceuticals by the batch. One study on stable isotopic composition of APIs, performed in collaboration with the FDA, showed that the isotopic provenance of 20 samples of four *Active Pharmaceutical Ingredients* APIs could be easily differentiated both by manufacturer and by individual batches on the basis of their bulk isotopic fingerprints. The study, called Stable Isotopic Characterization of showed the ability to trace pharmaceuticals isotopically.

This and another study employs multi-stable isotopic analysis (MSIA). This is seen as a forensic track-and-trace authentication method, which can be used in fighting various problems of counterfeiting and diversion. The technique does not need FDA

approval. MSIA relies upon the inherent properties of pharmaceutical materials themselves (ie their stable-isotopic composition), and thus does not require addition of taggants with inherent impurities. The MSIA technique is based on non-radioactive (stable) isotopes and is compatible with RFID and barcoding technologies.

252 Tracer Isotopes

There are at least 252 naturally-occurring stable isotopes in nature. A ratio of any two of those isotopes in a given pharmaceutical component can be used as a tracer of a product's identity. **Molecular Isotope Technologies** typically uses a combination of stable-isotope ratios of 3-4 elements (carbon, nitrogen, oxygen, and hydrogen) to act as tracers of product authenticity with its pharmaceutical and regulatory clients.

Another study, also conducted in cooperation with the FDA, showed that analysis of the stable isotopic

composition of a single API (naproxen) enabled the authors to determine significant differences in 26 blind samples. Thus, six manufacturers of naproxen from four different countries (Italy, India, Ireland, and the U.S.A.) were readily differentiated from the sample suite by their stable isotopic analysis.

There is agreement in the pharmaceutical community that it would cost more to counterfeit a given isotopic combination accurately than it would cost to purchase the product legally, said John P. Jasper, chief scientific officer of Molecular Isotope Technologies, an author of both reports. 'Thus there is virtually no incentive for identity fraud by replicating isotopic combinations,' he said.

Contact: John P. Jasper, Molecular Isotope Technologies, LLC, 8 Old Oak Lane, Niantic, CT 06357. Tel. 860 739 1926, fax 860 739 3250. www.molecularisotopes.com

Pharmacy Group Advises Public to Watch Drug Packaging

The American Society of Health-System Pharmacists (ASHP) is telling consumers to protect themselves from counterfeits by monitoring their drug packaging. The advice comes as part of a public service announcement made by the ASHP concerning the rising instances of counterfeits in the US. It supports the notion that a vigilant public is an effective tool in fighting counterfeits. ASHP also wrote that pharmacists play the key role in inspection. Pharmacists, however, have voiced

concerns over whether they can or should be responsible for role of authentication. The announcement reported that 'the best allies in receiving safe and appropriate drug therapy are pharmacists and physicians.'

'It is very difficult for patients to tell just by looking at a medication or its packaging if it is a counterfeit product,' said Daniel Ashby, ASHP president, noting the increasing sophistication of counterfeiters. 'However, that is not to say that con-

sumers are helpless in the face of this new threat.' ASHP recommends that consumers approach pharmacists if medication is different than experienced before in shape, color, taste, smell, or feel – or packaged differently.

ASHP is the 30,000-member US association that represents pharmacists who practice in hospitals, health maintenance organizations, long-term care facilities, home care and other components of health care systems.

Contact: www.ashp.org