ISOTECH®

www.isotechlabs.com mail@isotechlabs.com

Isotech Laboratories, Inc. 1308 Parkland Court Champaign, IL 61821-1826 Telephone 217/398-3490 FAX 217/398-3493

October 27, 2003

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

RE: Docket No. 2003N-0361, FDA Counterfeit Drug Meeting
Comments to the Task Force on the use of multi-element stable isotope analysis (MSIA) for forensic drug identification.

Dear Sir or Madam:

On October 15, 2003, I attended the Public Meeting in Bethesda on the FDA's Initiative Against Counterfeit Drugs. Because of the large number of participants in this meeting I was unable to contribute my thoughts and ideas, so I am doing so in the form of these Comments to the Task Force. This letter is to **respectfully urge the FDA Task Force on Drug Anti-Counterfeiting to recommend multi-element stable isotope analysis (MSIA) as a viable forensic method for combating drug counterfeiting in its final report.**

The FDA's approach to this problem clearly identified three levels of attack. It was pointed out that to adequately mitigate the potential danger, it will be necessary to develop "overt," "covert," and "forensic" methodologies for pharmaceutical identification and authentication. The vast majority of the vendors who gave presentations and who had exhibits were demonstrating overt methods of product identification. A few demonstrated covert technologies, but I saw only one vendor who was specifically targeting forensic technology and that was Dr. John Jasper of Molecular Isotope Technologies, LLC. Dr. Jasper demonstrated the applicability of using multi-element stable isotope analysis for pharmaceutical authentication.

Stable isotope analysis has been a standard tool in the geosciences for nearly 50 years, but only in the last 10 to 15 years has it come into common use in the consumer area. To a large degree this is the result of the recent improvements in instrumentation that allow rapid and inexpensive analysis of a variety of different isotopic species. There are several reasons why I believe that multi-element stable isotope analysis (MSIA) provides a very viable forensic tool in the fight against counterfeit drugs.

1. **Natural Fingerprints**. MSIA involves *analysis of the natural variations* in a chemical species, rather analogous in its specificity to DNA identification. Therefore, *absolutely nothing need be added* to the pharmaceutical to apply this

method. All that is needed is to compare an analysis of the sample in question to that of a sample of the authentic product. The method therefore does not compromise the product or impinge on product safety in any way.

2. **Currently in Use**. Stable isotope analysis is *currently in use for product identification and authentication* in several areas. For example, isotopic analysis can readily identify honey or maple syrup that has been diluted with corn syrup. Isotopic analysis is used to establish the provenance of wine and is even used to identify sources of illicit drugs. In fact, the FBI has recently funded a large research project to establish the source of castor beans (used to produce the terrorist-associated toxin ricin) using MSIA. The method is therefore *broadly accepted and extensively used*.
3. **Proven in Courts of Law**. Stable isotope analysis has become the standard methodology for differentiating natural gases from different sources and has been *frequently used to litigate disputes over ownership* of natural gas. It is therefore a method that has been accepted by our court system on numerous occasions.
4. **Available for Immediate Use**. MSIA is *commercially available* for immediate use. My company, which has been in business for over 18 years, specializes in stable isotope analysis and processes thousands of samples each year. Our automated state-of-the-art instrumentation allows rapid and accurate analysis of a variety of different materials for different isotopic species. Isotech has over 200 years of experience in isotopic analysis on staff.
5. **Highly Specific Identification**. MSIA has the *potential to be more specific* than virtually any other drug identification and authentication tool. In the FDA's own studies it has been clearly demonstrated that not only can samples of drugs from different manufacturers be differentiated, but even different batches from one manufacturer can be distinguished.

In light of the many of advantages of using multi-element stable isotope analysis for product identification, I strongly urge that the FDA Task Force on Drug Anti-Counterfeiting identify multi-element stable isotope analysis (MSIA) as a viable forensic method for combating drug counterfeiting in its final report.

Thank you for allowing me the opportunity to comment.

Sincerely yours,

Dennis D. Coleman, Ph.D.
President and Laboratory Director

Isotech Laboratories, Inc. 1308 Parkland Court Champaign, IL 61821-1826 Telephone 217/398-3490 FAX 217/398-3493