



BioVigilant Submits Drug Master Files to U.S. FDA, Accelerating Regulatory Approval Process for Instantaneous Microbial Detection Equipment Use

TUCSON, AZ—October 7, 2008--**BioVigilant Systems, Inc.**, (www.biovigilant.com), inventors of [Instantaneous Microbial Detection](#), today announced that the Company has submitted two Type V Drug Master Files (DMF) to the U.S. Food and Drug Administration (FDA) for its [IMD](#)(TM)-A product line, a family of products used for rapid environmental air monitoring in pharmaceutical environments. In support of customers' filings, these DMFs may now be referenced by pharmaceutical drug manufacturers who wish to use BioVigilant's systems in FDA-regulated applications.

BioVigilant's IMD-A systems immediately detect the presence of harmful bacteria in the drug manufacturing process, in contrast to traditional methods which can take as long as one week. As a result, IMD-A systems can eliminate the need for expensive reagents or lengthy delays in the delivery of drugs to the market while cultures are being grown.

Two other IMD-A design features offer drug makers a better tool in helping to prevent the release of contaminated product. As optical, laser-based devices, BioVigilant's IMD-A systems utilize naturally occurring fluorescence in bacteria and a principle called Mie Scattering to assess inert from biologic particles, on a single particle basis. This single particle analysis capability offers greater sensitivity in the detection of bacteria, in contrast to the limited operational ranges displayed by common types of traditional equipment, making them less sensitive at detecting low levels of bacteria. Secondly, IMD-A systems can be used to continuously monitor the environment as opposed to traditional methods that are used periodically for spot checks.

"Today's microbial culture methods are based on technology largely unchanged since Fanny Hesse introduced the use of agar for bacteriological medium in 1881, replacing potatoes and gelatin. FDA actively encourages use of new technologies including rapid microbiology methods," said Dr. David Hussong, FDA's Associate Director for New Drug Microbiology, Office of Pharmaceutical Science, CDER.

The DMF submissions contain confidential information the FDA accesses to approve the use of the rapid microbiological method enabled by BioVigilant's equipment in the manufacturing, processing, packaging or storage of drug products.

"BioVigilant is dedicated to helping drug makers realize the FDA's Process Analytical Technology (PAT) Initiative and the higher quality assurance standards being sought. Members of the IMD Consortium, consisting of twelve very forward-looking pharmaceutical companies, have helped us specify the system and now are engaged in various stages of system evaluation. The testing submitted as part of the DMF required highly specialized aerosol science expertise not readily available outside of government test labs," said Deward Manzer, CEO of BioVigilant Systems, Inc. "We believe this testing, in conjunction with our customers' validation testing, will offer a very comprehensive view on the power of the IMD-A technology and will accelerate adoption across the pharmaceutical industry," he added.

The next meeting of the IMD Consortium will coincide with the PDA third annual Global Conference on Pharmaceutical Microbiology being held in Chicago October 20-23.

About BioVigilant

With headquarters in Tucson, Arizona, BioVigilant Systems invented instantaneous microbial detection technology to address environmental monitoring needs in the pharmaceutical, biotechnology, healthcare, and environmental applications. BioVigilant's IMD systems detect - instantaneously and in real-time - particulate count, size, and biological status. Unlike other rapid microbial methods, BioVigilant's optically-based systems require no staining, no reagents, no waiting period, and little human intervention. The company holds 20 patents with an additional 25 applications pending. For more information, go to www.biovigilant.com.

Trademark Notice

BioVigilant, the Biovigilant logo, IMD, and IMD-A are trademarks of BioVigilant Systems.

For More Information

Contact Mary Parsons, BioVigilant Systems, mparsons@biovigilant.com, 520-292-2342.