US FDA and GMP Compliance

Daniel Fabricant, Director of the Food and Drug Administration's (FDA) Division of Dietary Supplement Programs, recently told attendees of the American Herbal Products Association's (AHPA) inaugural Botanical Congress in New York that industry companies can expect more inspections, more injunctions, and more product seizures from FDA related to current good manufacturing practice (cGMP) violations.

Mr Fabricant said FDA conducted 175 inspections in 2011, filed its first injunction, and seized products for the first time. In 2012, he noted that 138 inspections were already "under our (FDA) belt." The most common areas of cGMP non- compliance discovered during FDA investigations, included:

- Failure to prepare a master manufacturing record
- Failure to prepare a batch record
- Failure to establish specifications
- Failure to determine if specifications are met
- Failure of adequate quality control

Source: AHPA