US: New GMP guidance for small businesses

FDA has prepared a 'Small Entity Compliance Guide on Current Good Manufacturing Practice in manufacturing, packaging, labelling, or holding operations for dietary supplements'.

Such guidance documents do not establish legally enforceable responsibilities, but do describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

Source: CRN US

FDA WARNINGS

- *FDA warning on GMP failures*

Following initial scrutiny of the manufacturing process for several herbal tea products, Food and Drug Administration (FDA) officials have sent a warning letter to the manufacturer saying employees at the plant did not meet some required manufacturing practice rules for dietary supplements.

An FDA spokeswoman said the company would need to show what employees would do to correct the problems. Companies that receive "warning letters", the initial step in the FDA's process towards enforcement, then go back on the short-list to be re-inspected.

- *FDA warning on illegal ingredients*

The US Food and Drug Administration (FDA) has received multiple reports of adverse events associated with the use of a weight-loss product marketed as dietary supplement, including several cardiac events and one death.

On analysis, the product was found to contain sibutramine, a controlled substance that was withdrawn from the market in October 2010 for safety reasons. The product poses a threat to consumers because sibutramine is known to substantially increase blood pressure and/or pulse rate in some patients and may present a significant risk for patients with a history of coronary artery disease, congestive heart failure, arrhythmias or stroke.

- *FDA warning on labelling/claims*

The FDA has warned a company marketing a number of their herbal products, including Goji Berries, Mesquite Pod Meal, Milk Thistle Seed Powder, Rice Bran, Acai Powder, and Yacon Syrup products are in violation of the food labelling regulations, and that the company's website promotes these products for conditions that cause them to be drugs because they are intended for use in the cure, mitigation, treatment or prevention of disease.

- *FDA warning on caffeine-containing drinks for sexual enhancement and interaction with medicines*

The FDA has advised consumers not to buy or use certain brands of caffeine-containing drinks sold as supplements for sexual enhancement as they contain an active ingredient that could interact with medications that include nitrates, lowering blood pressure to 'dangerous levels'.

Source: AHPA