US FDA unveils new global strategy for imported products

The U.S. Food and Drug Administration has now unveiled a new strategy to meet the challenges posed by rapidly rising imports of FDA-regulated products and a complex global supply chain in a report called the "Pathway to Global Product Safety and Quality."

"Global production of FDA-regulated goods has exploded over the past ten years. In addition to an increase in imported finished products, manufacturers increasingly use imported materials and ingredients in their U.S. production facilities, making the distinction between domestic and imported products obsolete," said Commissioner of Food and Drugs Margaret A. Hamburg, M.D. "*There has been a perfect storm - more products, more manufacturers, more countries and more access. A dramatic change in strategy must be implemented."*

The report calls for the FDA to transform the way it conducts business and to act globally in order to promote and protect the health of U.S. consumers. Four key elements needed to make this change are highlighted:

- The FDA will partner with its counterparts worldwide to create global coalitions of regulators focused on ensuring and improving global product safety and quality.

- The coalitions of regulators will develop international data information systems and networks and increase the regular and proactive sharing of data and regulatory resources across world markets.

- The FDA will build in additional information gathering and analysis capabilities with an increased focus on risk analytics and information technology.

- The FDA increasingly will leverage the efforts of public and private third parties and industry and allocate FDA resources based on risk.

Source: AHPA