



FDA: International Regulators, Industry and Import Safety

You are aware that an increasing number of products – especially those affecting your health, like food and medical products – are being imported from beyond our borders. This has raised great concern recently about FDA's ability to ensure the safety of those products. This week, I attended a summit with hundreds of industry leaders to collectively address the challenges of product safety in a global market place.

My take is that the challenge of imported product safety will increase because as American consumers, we have come to expect - and even demand - year round variety in the food we eat. And because the production of many of the drugs and medical devices we use is now a global enterprise. So if we are going to want safety in all these products, it will require a collective effort, through collaboration with

industry and international regulatory counterparts. This is to build safety in to the production of food and medical products as well as to create systems that assure their safety through distribution and consumption.

That's why the FDA is accelerating initiatives like our participation in a groundbreaking program with partners in the European Union and Australia. Through a new pilot program we will jointly plan, allocate, and conduct certain inspections of facilities in developing countries that manufacture the starting materials for many of the drugs you take. If this program is successful, it could be expanded to include other types of drug manufacturing facilities. By leveraging the resources of each agency and sharing vital information, the number of foreign facilities in our inspection data base expands while allowing FDA to target its resources on products that we believe present the highest risk to US consumers.

We are also looking at new

ways to work more closely with industry to protect our food supply. This week, we announced a pilot program for third-party certification of aquacultured shrimp, and we issued a draft document that when finalized will describe standards for third party certification programs for other food and animal feed products.

International collaboration, building new systems with trusted partners, and working closely with the private sector are all elements of our FDA Beyond our Borders initiative, our Food Protection Plan, and the Import Safety Action Plan. Through these initiatives, we are setting the course for the FDA of the 21st century. As always, this is being done to support our regulatory mission to keep you and your family safe – while you enjoy what the amazing and growing global marketplace has to offer.



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