

## A Call to Action Opening FDA Offices in India



**Office of International Programs**  
**Office of the Commissioner**  
**Food and Drug Administration**  
**U.S. Department of Health and Human Resources**



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## Challenges of Globalization

Globalization has fundamentally changed the environment for regulating food and medical products

Created unique regulatory challenges for FDA:

- More foreign facilities supplying the U.S.;
- Increasing volume of imported products;
- More outsourcing of manufacturing and clinical trials;
- Greater complexity in supply chains;
- Growing complexity of products and manufacturing methods;
- Imports coming from countries with less well developed regulatory systems; and
- Greater opportunities for economic fraud.

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**Pet Food Contained Chemical Found in Plastic, F.D.A. Says**



**China Acts on Food Safety After Pet Poisonings**



**104 Deaths Reported in Pet Food Recall**



**Gluten factory had a toxic history**

**China detains manager at heart of U.S. pet food recall**

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## Objectives of FDA Global Presence

- (1) Gather better knowledge *in-country* about the production of these products and their transport to U.S. ports
- (2) Engage with *trusted* counterpart agencies overseas to leverage scientific, inspectional, and other resources
- 3) When requested, engage with *developing* counterpart agencies to help build their capacity
- (4) Engage private- and public-sector *trusted third parties* to provide helpful information about regulated industry compliance with FDA standards

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## The Frightening Heparin Case



China may be source of tainted heparin

FDA cites Chinese firm's  
manufacturing processes for heparin

China Orders New Oversight of Heparin



U.S. Identifies Tainted Heparin in 11 Countries

## Indian Office Staffing Plans

### New Delhi Office:

- Country Director
- Deputy Director
- 1 Senior Technical Experts (medicines)
- 2 Senior Technical Experts (foods)
- 2 Senior Technical Expert (medical devices)

### Mumbai Office:

- 5 Consumer Safety Officer/Inspectors

## Key India Office Tasks

- Further strengthen a trusted regulator-to-regulator relationship
- Learn more about the industries that wish to export to the USA and help them understand U.S. expectations for that exported product
- More easily inspect manufacturing and processing facilities
- Help verify that products exported to the USA and the way they are manufactured meet U.S. health and safety requirements
- *When requested*, to collaborate with counterpart food and medical product agencies to improve product safety.

## Indian Imports To U.S. Increasing

- **Medicines:** Indian companies reportedly exported \$1.38 billion worth of medicines to the U.S. in 2007-08.
  - Growth is also impressive — 39 per cent (in dollar terms) per annum in recent years.
  - Of the 6,300 active drug master files (files from manufacturers of various components of finished dosage forms), FDA maintains, about 26 per cent (or about 1,700) are from Indian companies
  - India has more FDA-approved plants than any other country
- **Foods:** India shipped \$1.4 billion in foods to the United States last year (mainly shrimp, cashews, spices and tea).

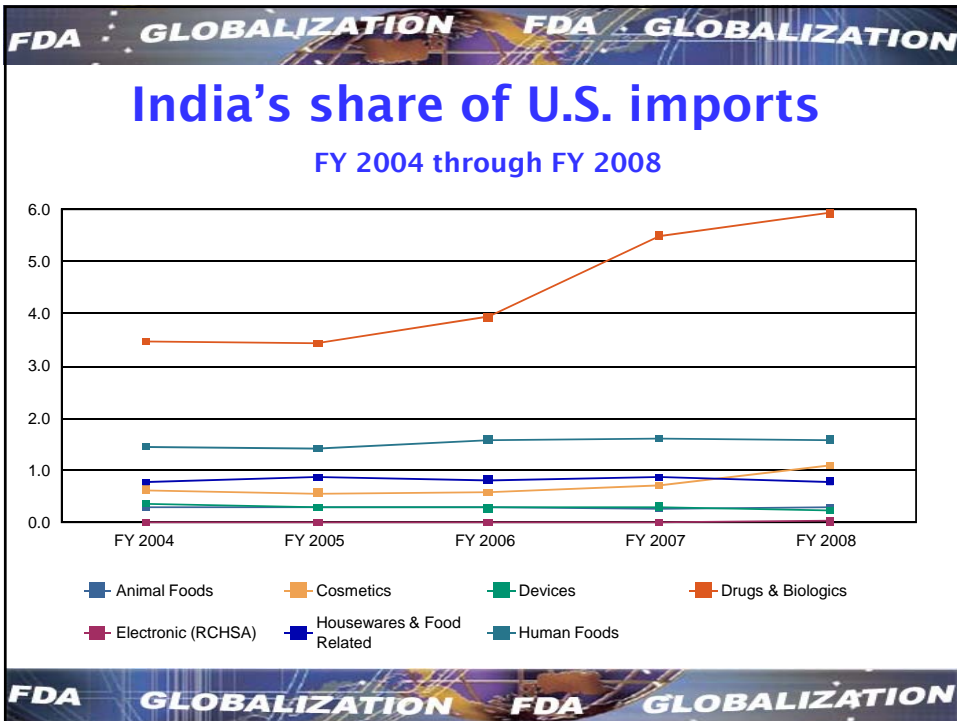
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## Product Imports from India

- Drugs – India ranks 4<sup>th</sup> in volume (6.0%)
- Foods – India ranks 8<sup>th</sup> in volume (0.9%)
- Devices – India ranks 25<sup>th</sup> in volume (0.3%)
- Cosmetics - India ranks 14<sup>th</sup> in volume (0.7%)
- Animal Feeds - India ranks 15<sup>th</sup> in volume (0.2%)
- Electronics\* - India ranks 34<sup>th</sup> in volume (0.01%)

\*X-ray systems, TVs and monitors with cathode ray tubes, microwave devices, lasers, tanning beds, etc. Includes electronic radiation-based medical devices.

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*Thank you*

Questions or Comments

Bruce Ross, MA MPH

➤ E-mail: [bruce.ross@fda.hhs.gov](mailto:bruce.ross@fda.hhs.gov)