82nd Annual TPHA Conference

Lessons Learned
Foreign Country Donations of Food & Drugs
Hurricanes Katrina & Rita
&
ORA’s Transformation

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And Then The Storm Came…

• Hurricanes Katrina and Rita - ‘Caused A Whole Lot of Harm; And, For Many Months, Nothing Was Easy.’
Lessons Learned

- When Disasters Strike
  - Chain of Command for Response
  - Priorities Change
  - Resources Shift
  - Communication Technology
  - The Act (It’s The Law)
- Transformation
  - Revisit
  - Revise
  - Renew

When Disasters Strike

- Chain of Command for Response
- Priorities Change
- Resources Shift
- Communication Technology
When Disasters Strike (cont)

• Priorities
  – Employee Safety
  – Consumer Safety
  – Refocusing Investigations In The Disaster Areas

• Resources
  – Deployments
  – Travel Dollars

When Disasters Strike (cont)

• Resources
  – Deployments
  – Travel Dollars

• What did we learn:
  – That communication is key in deployments
  – The heart of the employee to extend themselves to make things work is what often times makes us successful
When Disasters Strike (cont)

• Tent City - Housing/Sleeping Quarters

• We Learned/Reinforced What We Knew:
  – We Have A Great Dedicated Staff, Willing To Live & Work Under Adverse Conditions To Get The Job Done!
  – It’s Not Always Easy!!

When Disasters Strike (cont)

• Staff Shortages Created in Critical Areas Due to Deployments
  – Lesson Learned: Have A Plan In Place To Stagger Deployment of Personnel
When Disasters Strike (cont)

• Communication Technology
  – Communication between Agency Organizational Components Was Highly Effective
  – Data Was Shared Routinely & Quickly
  – Needed Guidance from Headquarters To Field Was Received
• Recommended Improvements
  – Alternate Forms of Communication Equipment

When Disasters Strike (cont)

• Interaction with Other Agencies
  – We Performed Well with HHS Agencies
    • Probably Due to Common Aspects of Agency Missions
  – Communications on Deployment Was Somewhat Lacking
• Recommendations:
  – Up-to-Date Database Lists of Volunteers And Their Skill Sets
  – Inoculation Policy
  – Training for Disasters
Procedures & Policies

• Procedures & Policies - Donated Goods And Government-to-Government Shipments
  – The Act (It’s The Law)
    • 801(a) Entry Data
    • 801(m) Prior Notice Information

Procedures & Policies (cont)

• Government-to-Government Shipments
  – FEMA/DOS/USAID Taskforce Is Addressing This Issue
  – Even In A Disaster, We Must Continue To Protect The Consumer Through Well Designed Procedures That Emphasize Safety As Well As Compassion & Humanitarian Relief
  – Have FDA At The Table Prior to Any Temporary Wavier of Filing of Import Entry Documents
Transformation

• Transformation
  – Revisit
  – Revise
  – Renew
• As The World In Which We Live And Work Changes, We Must Change

Transformation (cont)

• Imports
  – Consider How Best To Implement FDA’s Import Strategy, Including Aligning ORA’s Organizational Structure And Funding Priorities with This Strategy
  • Risk Based Targeting – Life Cycle of The Product
  • Identify Structure And Function To Achieve Goals of the Import Strategy
Transformation (cont)

• Import Strategy – Five Workgroups
  – Foreign Operations
  – Border Operations and Entry Admissibility
  – Imported Goods In Domestic Commerce
  – Information Technology
  – Applied Science and Technology

To Summarize…

• We Have Learned To:
  • Seize The Moment and Act
  • Review What We Did
  • How We Did It
  • Acknowledge Our Successes
  • Recommend Needed Changes
  • Implement Needed Changes
  • Prepare and Plan for the Next Big One!

AND

Never Forget It Takes A Team To Sustain Us, and Make Us Successful In Our Mission!
Questions

• Q & A