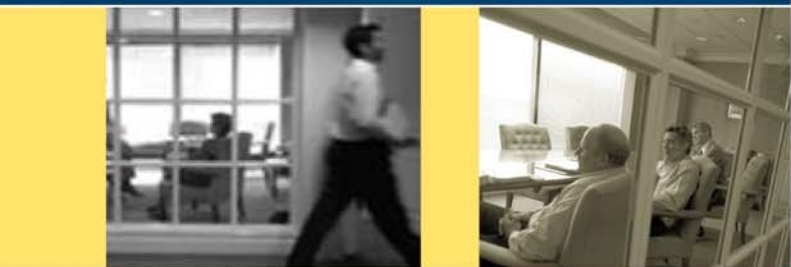




# Antimicrobial Inert Ingredient Issues

Sue Crescenzi  
Sr. Regulatory Analyst



STEPTOE & JOHNSON<sup>LLP</sup>

[steptoe.com](http://steptoe.com)

February 4, 2010

# Important Issues

- Process for review and approval
- Time required for review
- “Green” chemistries
- Fragrances

# Review and Approval

- Symposium has been helpful in clarifying process
- No PRIA categories for antimicrobial products with unapproved inerts
  - Seek inert ingredient approval prior to submission of application
  - Uncertainty about time to obtain approval of both food and non-food inerts

# Green Chemistry

Sustainability is the new watch word

What is a sustainable inert ingredient

- Low toxicity to applicators and bystanders

- No environmental concerns

DfE pilot program

- Pilot limited to antimicrobial products

- May require some new evaluation criteria for active ingredients

# Fragrances

- What makes fragrances a special case?
- Fragrance Ingredient List
  - The tool box approach
- Fragrance Notification Program
- Tolerance exemptions
  - A remaining challenge