

**Final Questions - May 11, 2001**  
**Joint Meeting - Nonprescription Drugs Advisory Committee &**  
**Pulmonary - Allergy Drugs Advisory Committee**

1. **Does loratadine have a safety profile acceptable for OTC marketing , i.e., can it be used safely without a learned intermediary?**
  - a. If no, what safety or other clinical issues should be addressed prior to OTC marketing?
  - b. If yes, what statements, related to sedation or any other safety issues should be included in OTC labeling?
  
2. **Does fexofenadine have a safety profile acceptable for OTC marketing , i.e., can it be used safely without a learned intermediary?**
  - a. If no, what safety or other clinical issues should be addressed prior to OTC marketing?
  - b. If yes, what statements, related to sedation or any other safety issues should be included in OTC labeling?
  
3. **Does cetirizine have a safety profile acceptable for OTC marketing , i.e., can it be used safely without a learned intermediary?**
  - a. If no, what safety or other clinical issues should be addressed prior to OTC marketing?
  - b. If yes, what statements, related to sedation or any other safety issues should be included in OTC labeling?