

# Meeting Information Sheet for September 5, 2002

Pulmonary-Allergy Drugs Advisory Committee; Notice of Meeting

The meeting will be open to the public.

Date and Time: September 6, 2002, from 7:30 a.m. to 4 p.m.

Location: Holiday Inn, The Ballroom, 2 Montgomery Village Avenue, Gaithersburg, MD.

Contact Person: Kimberly Littleton Topper, Center for Drug Evaluation and Research, HFD-21, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, (for Express delivery: 5630 Fishers Lane, Room 1093, Rockville MD 20857), (301) 827-7001, or by e-mail at [topperk@cder.fda.gov](mailto:topperk@cder.fda.gov)

Agenda: The committee will discuss new drug application (NDA) 21-395, Spiriva (Tiotropium bromide) by Boehringer-Ingelheim for chronic obstructive pulmonary disease (COPD).

## **To Present at the Open Public Hearing:**

Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. **Oral presentations** from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify Kimberly Topper **before September 1, 2002**, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation (10 minutes is the top limit - expect 5 minutes). The deadline for submitting electronic presentation to be used at the OPH is September 1. Please e-mail these presentations to [topperk@cder.fda.gov](mailto:topperk@cder.fda.gov).

Written submissions may be made to the contact person by **September 1, 2002**. Send to the contact address above.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Kimberly Topper at least 7 days in advance of the meeting. Dated 5 August 2002

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Kimberly Topper

Executive Secretary