DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pulmonary-Allergy Drugs Advisory Committee; Republishing of Meeting Notice

AGENCY: Food and Drug Administration. **ACTION:** Notice.

summary: The Food and Drug Administration (FDA) is republishing a portion of the notice announcing a meeting of the Pulmonary-Allergy Drugs Advisory Committee scheduled for May 13, 1983. The meeting was announced in the Federal Register of April 29, 1983 [48 FR 19470). This portion of the notice is being republished because of a revised schedule and a change in the open committee discussion concerning sulfiting agents used as antioxidants in drug products and the pharmacokinetics and labeling of sustained release theophylline preparations. These topics will be scheduled for discussion at an advisory committee meeting to be announced later for June 1983. The May 13 meeting will deal solely with the over-the-counter status of metaproterenol metered dose inhalers. These inhalers do not contain sulfiting

Pulmonary-Allergy Drugs Advisory Committee

Date, time, and place. May 13, 8 a.m., Conference Rm. 10, Bldg. 31, National Institutes of Health, 9000 Rockville Pike, Bethesda, MD.

Type of meeting and contact person.
Open public hearing, 8 a.m. to 9 a.m.;
open committee discussion, 9 a.m. to 4
p.m.; Conrad J. Leder, National Center
for Drugs and Biologics (HFN-160), Food
and Drug Administration, 5600 Fishers
Lane, Rockville, MD 20857, 301-4433500.

General function of the committee.
The committee reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in the treatment of pulmonary disease and diseases with allergic and/or immunologic mechanisms.

Agenda—Open public hearing.
Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee.

Open committee discussion. The committee will discuss whether metaproterenol metered dose inhalers should continue to be marketed over-the-counter (OTC).

Dated: May 4, 1983.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

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