Food and Drug Administration
Center for Drug Evaluation and Research

Summary Minutes of the
**Pulmonary-Allergy Drugs Advisory Committee**

June 14, 2005
620 Perry Parkway, Gaithersburg, Maryland

**Pulmonary-Allergy Drugs Advisory Committee Members Present (Voting):**
Erik R. Swenson, M.D.
Mark L. Brantly, M.D.
Steven Gay, M.D., M.S.
Carolyn M. Kercsmar, M.D.
Fernando D. Martinez, M.D.
I. Marc Moss, M.D.
Lee S. Newman, M.D.
Calman P. Prussin, M.D.
Michael Schatz, M.D., M.S.
David A. Schoenfeld, Ph.D.

**Pulmonary-Allergy Drugs Advisory Committee Consultants (voting):**
Karen Schell, RRT (Consumer Representative)
Jacqueline S. Gardner, Ph.D., M.P.H.
Nancy J. Sander (Patient Representative)

**Industry Representative (non-voting):**
Theodore Reiss, M.D. was invited but unable to attend due to an urgent family matter.

**Pulmonary-Allergy Drugs Advisory Committee Members Absent:**
Peter E. Morris, M.D.
William J. Calhoun, M.D

**FDA Participants:**
Robert Meyer, M.D.
Badrul Chowdhury, M.D.
Eugene J. Sullivan, M.D., FCCP

**Open Public Hearing Speakers:**
Maureen Hardwick
Kirk Shepard, M.D.
Alan Krueger, M.S.
Leslie Hendeles, Pharm.D.

**Executive Secretary**
Teresa A. Watkins

I certify that I attended the July 14, 2007 meeting of the Pulmonary-Allergy Drugs Advisory Committee and that these minutes accurately reflect what transpired.

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| _____ | _____ |
| Teresa A. Watkins | Erik R. Swenson, M.D. |
| Executive Secretary, PADAC | Chair, PADAC |

**Quick Minutes**
**Pulmonary-Allergy Drugs Advisory Committee Meeting**
**July 14, 2005**

A verbatim transcript will be available in approximately two weeks, sent to the Division and posted on the FDA website at:

All external requests for the meeting transcripts should be submitted to the CDER, Freedom of Information office.

Prior to the meeting, the members and the invited consultants were provided the background material from the FDA. The meeting was called to order by Erik R. Swenson (Chair, PADAC); the conflict of interest statement was read into the record by Teresa Watkins (Executive Secretary). There were approximately 100 persons in attendance. There were 4 speakers for the Open Public Hearing Session (see below for a listing of the speakers).

**Attendance:**
**Pulmonary-Allergy Drugs Advisory Committee Members Present (voting)**
Erik R. Swenson, M.D., Mark L. Brantly, M.D., Steven Gay, M.D., M.S., Carolyn M. Kercsmar, M.D., Fernando D. Martinez, M.D., I. Marc Moss, M.D., Lee S. Newman, M.D., Calman P. Prussin, M.D., Michael Schatz, M.D., M.S., David A. Schoenfeld Ph.D..

**Pulmonary-Allergy Drugs Advisory Committee Consultants (voting):**
Karen Schell, RRT (Consumer Representative), Nancy J. Sander (Patient Representative).

**Industry Representative (non-voting):**
Theodore Reiss, M.D. was invited but was unable to attend due to an urgent family matter.

**Pulmonary-Allergy Drugs Advisory Committee Members Absent:**
Peter E. Morris, M.D., William J. Calhoun, M.D.

**FDA Participants:**
Robert Meyer, M.D., Badrul Chowdhury, M.D., Eugene J. Sullivan, M.D., FCCP,

**Open Public Hearing Speakers:**
Maureen Hardwick, Kirk Shepard, M.D., Alan Krueger, M.S., Leslie Hendeles, Pharm.D.

**Issue:**
The committee discussed **the** continued need for the essential use designations of prescription drugs for the treatment of asthma and chronic obstructive pulmonary disease under 21 CFR 2.125.

**The agenda proceeded as follows:**

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| Call to Order and Opening Remarks | Erik R. Swenson, M.D.<br>Chair, Pulmonary-Allergy Drugs Advisory Committee |
| Introduction of Committee | |
| Conflict of Interest Statement | Teresa A. Watkins, R.Ph.<br>Executive Secretary, PADAC |
| FDA Introductory Remarks/<br>Plaque Presentation | Robert Meyer, M.D.<br>Director, Office of Drug Evaluation II |
| **FDA Presentation** | |
| The Montreal Protocol and the status of Essential Use process (21 CFR 2.125) | Robert Meyer, M.D.<br>Director, Office of Drug Evaluation II |
| Clarifying Questions | Committee |

**Open Public Hearing**

**Committee Discussion**

Given the existing pharmaceutical market and the current practice of medicine, do the products in List A below remain essential uses of CFCs? Bear in mind that if you advise us that a product is no longer essential, for FDA to affect that advice, we still must hold an open public meeting and go through notice and comment rulemaking, meaning the public and other concerned parties would have the ability to weigh in on the proposed delisting.

To aid in your deliberations over whether individual moieties remain essential, it is important for you to know what moieties still are marketed in CFC-containing products and listed under 21 CFR 2.125(e) as essential, as well as what products are currently approved and/or marketed that do not contain CFCs. Therefore List A below includes those moieties for which there are no current reformulations or direct alternative products and therefore are relevant to today's discussion under 21 CFR 2.125(g)(2). Other products currently listed under section 2.125(e) may be currently unavailable for other reasons, and therefore could be de-listed under alternative criteria (see sections 2.125(g)(1) or 2.125(g)(3)). Also I have provided a list of potentially relevant marketed non-CFC products to help you consider whether the moieties cited in List A remain essential (List B).

LIST A. Moieties currently listed under 21 CFR 2.125(e) for which no current reformulated or direct alternative product exists:

**1. Beta-agonists***

- metaproterenol (Alupent)
  Essential = 0
  Non-Essential = 11
  Abstain = 1
  Total = 12

- pirbuterol (Maxair)
  Essential = 0
  Non-Essential = 10
  Abstain = 2
  Total = 12

**2. Inhaled Corticosteroids**

- flunisolide (Aerobid)
  Essential = 0
  Non-Essential = 11
  Abstain = 1
  Total = 12

- triamcinolone (Azmacort)
  Essential = 0
  Non-Essential = 11
  Abstain = 1
  Total = 12

**3. Cromones**

- Cromolyn (Intal)
  Essential = 6
  Non-Essential = 4
  Abstain = 2
  Total = 12

It was stated that there is a niche in which this medication has a role (i.e. exercise-induced bronchospasm in patients who do not tolerate beta-agonists and prevention of episodic allergy-induced bronchospasm).

- Nedocromil (Tilade)
  Essential = 0
  Non-Essential = 11
  Abstain = 1
  Total = 12

**4. Albuterol/Ipratropium (Combivent)**

Essential = 5
Non-Essential = 5
Abstain = 2
Total = 12

*Note that epinephrine would also be correctly included in this list. However, since this is an OTC drug product, this moiety will need to be separately considered so that the Advisors can properly include members of the Non-prescription Drugs Advisory Committee. FDA plans to hold a subsequent, timely meeting to specifically discuss epinephrine and the issue of OTC rescue bronchodilator availability.

11:a.m. Adjourn