



FDA Public Workshop on Phase Out of CFC-Propelled Epinephrine Inhalation Aerosol

September 25, 2009

Background: The FDA announced withdrawal of over-the-counter epinephrine (OTC) metered dose inhalers (MDIs) – brand name Primatene Mist™ – effective December 31, 2011. The agency's Center for Drug Evaluation and Research Advisory Committee convened a meeting to obtain public comment on issues related to the transition.

Issues and Summary of Reports:

1. What is known about current OTC epinephrine MDI usage? Who uses them and under what circumstances? Speakers speculated that people use them in emergencies or because they cannot afford physician care, but offered little evidence. Speakers discussed the challenges of using MDIs. The medical experts focused on the danger of relying on this product to control chronic asthma, and the danger self-care, not seeking an accurate diagnosis with care supervised by a physician who can prescribe treatments for both inflammation and bronchial spasms. Note: one presenter offered some studies supporting the notion that inhaled epinephrine might be nearly as helpful for mild episodic asthma symptoms as inhaled albuterol.
2. What sales data are available and what do they indicate about use of OTC epinephrine MDIs? The manufacturer, Amphastar Pharmaceuticals reported that the company sold 4.5 million units per year and estimates 2-3 million users. Top sales states are Tennessee, Virginia, California, Texas, and Florida. FDA is now seeking detailed sales figures.
3. What treatment alternatives are available for consumers who must switch from OTC epinephrine MDIs? Amphastar Pharmaceuticals announced that it has a new OTC epinephrine MDI before the FDA for approval, and hopes to have it in production in the 2011 – 2012 timeframe. Presumably, it will also be an OTC product. It will be more expensive than the current product. One speaker pondered whether “no treatment is better than inadequately supervised treatment”, and lamented the lack of data to support this assertion. He also recommended making refills of combination corticosteroids+albuterol products available without a new prescription but said that proper technique must be assured.
4. What are effective outreach strategies for informing consumers who use OTC epinephrine MDIs about the transition? Delivering messages is complicated when we have not defined the nested population of users, and drug stores have inconsistent policies for refilling albuterol inhaler prescriptions in an emergency. A health communications expert recommended three simple messages to the general public:
 - The CFC propelled epinephrine MDIs will not be available after December, 2011 (this message will be placed on the remaining *Primatene Mist* labels)
 - If you have asthma or COPD and are wheezing or having trouble breathing, you need to see a doctor
 - The best medications to treat asthma or COPD require a prescription.
5. What other education efforts should FDA undertake to effect an orderly transition? Other education recommendations included collaboration with manufacturers/distributors, patient groups, and other federal agencies, using social media and YouTube. FDA presented preliminary plans for public service announcement and releases on its website.

Prepared by Charlotte W. Collins, 10/09

FDA Public Workshop Agenda
Phase Out of CFC-Propelled Epinephrine Inhalation Aerosol
September 25, 2009
8:30 AM – 3:00 PM

Program

- 8:30 AM Welcome
Andrea Leonard Segal, M.D.
Director, Division of Nonprescription Clinical Evaluation, FDA
- 8:40 AM Introduction and Background of CFC-Propelled Epinephrine Inhalation Aerosol
Phase Out
Badrul Chowdhury, M.D., Ph.D.
Director, Division of Pulmonary and Allergy Products, FDA
- 9:15 AM Asthma, Epinephrine, and Therapeutic Alternatives
Leslie Hendeles, Pharm. D.
Professor of Pharmacy and Pediatrics
University of Florida
- 10:00 AM Perspective on the Underserved Population
Marcus Reidenberg, M.D.
Professor of Medicine, Pharmacology, and Public Health
Weill Cornell Medical College
- 10:45 AM Epinephrine Use and Communication Plan
Stephen Campbell, Esq.
Senior Vice President, Regulatory Affairs,
Amphastar Pharmaceuticals, Inc.
- 11:05 AM Communication Challenges
Ruth Parker, M.D.
Professor of Medicine
Emory University
- 11:30 AM Educating the Public On the Phase-Out of Epinephrine CFC Inhalers
Ellen Frank
Office of Communications, FDA
- 1:00 PM Open Public Session
- 1:30 PM Roundtable Discussion
- 2:30 PM Question and Answer Session