

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-007

Other Reviews

**REGULATORY PROJECT MANAGER LABELING REVIEW
(PHYSICIAN LABELING RULE)**

Division of Pulmonary and Allergy Products

Application Number: NDA 22-007

Name of Drug: Perforomist (formoterol fumarate dehydrate) Inhalation Solution

Applicant: Dey, L.P.

Material Reviewed:

Submission Date(s): April 26, and May 2, 2007

Receipt Date(s): April 27, and May 4, 2007

Submission Date of Structure Product Labeling (SPL): May 2, 2007

Type of Labeling Reviewed: SPL

Background and Summary

NDA 22-007 was tentatively approved on April 27, 2007, for the use of Perforomist Inhalation Solution in the long-term, twice daily (morning and evening) administration in the maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema. When the tentative approval letter issued, Dey had not submitted labeling in SPL format. Labeling in SPL format was submitted May 2, 2007.

Review

I compared the labeling for the Package Insert and Medication Guide dated May 2, 2007, to the Package Insert and Medication Guide labeling dated April 26, 2007. The labeling dated May 2, 2007, is identical to the labeling dated April 26, 2007, with the following minor exceptions:

1.

2.

b(4)

3. The company name and phone number were added to the second sentence under the ADVERSE REACTIONS section of the Highlights of Prescribing Information.
4. Under Full Prescribing Information: Contents, the following statement was added above number 1, "WARNING: INCREASED RISK OF ASTHMA-RELATED DEATH."
5. The words "Of Perforomist" were added after Excessive Use under Section 5 WARNINGS AND PRECAUTIONS subsection 5.3.

Conclusions

The labeling dated May 2, 2007, is acceptable.

Akilah Green, MS, RN
Senior Regulatory Management Officer

Supervisory Comment/Concurrence:

Sandy Barnes
Chief, Project Management Staff

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Akilah Green

5/11/2007 11:18:20 AM

CSO