DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-007

Dey, L.P.
2751 Napa Valley Corporate Drive
Napa, California 94558

Attention: Michelle A. Carpenter, JD
Vice President, Regulatory and Clinical Affairs

Dear Ms. Carpenter:

Please refer to your new drug application (NDA) dated June 28, 2007, received June 29, 2007, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Perforomist (fomoterol fumarate) Inhalation Solution 20 mcg/2 mL.

We acknowledge receipt of your submissions dated September 28, October 12, 18, and 19 (2), November 6, and 21, 2006, January 25, February 7, 9, 13, and 23, March 15, 28, and 29, and April 9, 13, 17, 20, 24, 26, and 27, and May 1, and 2, 2007.

The May 1, 2007, submission constituted a complete response to our April 27, 2007 action letter.

This new drug application provides for the use of Perforomist Inhalation Solution 20 mcg/2 mL for 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.

We have completed our review of this/these application, as amended. It is approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on May 2, 2007.

Please submit the final printed carton and container labels electronically that are identical to the carton and immediate container labels submitted on May 2, 2007. Alternatively, you may submit 12 paper copies of the final printed carton and container labels as soon as they are available but no more than 30 days after they are printed. Individually mount 6 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 22-007**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and

effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

We remind you of your post-marketing study commitments in your submission dated January 25, and March 30, 2007. These commitments are listed below.

1. To conduct a post-marketing safety and tolerability study with one or more doses and one or more dose levels of Perforomist Inhalation Solution in children with asthma and/or obstructive airway disease. The proposed study design is a 2-week, placebo or active controlled study with Perforomist Inhalation Solution BID in approximately 100 patients 12 years of age and younger.

Protocol Submission:	by January 31, 2008
Study Start:	by April 30, 2008
Final Report Submission:	by July 30, 2009

2. To conduct a post-marketing safety and efficacy study with one or more doses and one or more dose levels of Perforomist Inhalation Solution in children 12 years of age and younger presenting with an acute exacerbation of asthma.

Protocol Submission:	by March 27, 2009
Study Start:	by July 27, 2009
Final Report Submission:	by November 27, 2011

3. To conduct a post-marketing multi-center, randomized, placebo-controlled, large, simple safety study to evaluate the effects of long term use of Perforomist Inhalation Solution in patients with COPD. The objective of this trial would be to determine the risk of fatal and life-threatening respiratory events associated with the long term use of Perforomist Inhalation Solution in patients with COPD.

Protocol Submission:	by February 27, 2008
Study Start:	by June 27, 2008
Final Report Submission:	by June 27, 2012

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Postmarketing Study Commitment Protocol**", "**Postmarketing Study Commitment Final Report**", or "**Postmarketing Study Commitment Correspondence**."

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Ms. Akilah Green, Senior Regulatory Management Officer, at (301) 796-1219**.**

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Director
Division of Pulmonary and Allergy Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure

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

/s/

Badrul Chowdhury
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