CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-007

APPROVABLE LETTER

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 dated June 28, 2006, received June 29, 2006, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Perforomist (formoterol fumarate dehydrate) Inhalation Solution 20mcg/2 mL.

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

This NDA provides for the use of Perforomist Inhalation Solution 20mcg/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 completed our review of this application, as amended. It is tentatively approved under 21 CFR 314.105 for use as recommended in the agreed-upon labeling text including the minor editorial revisions indicated in the enclosed package insert, the medication guide submitted April 26, 2007, (copy enclosed), the foil and carton labels submitted April 20, 2007, with the revisions agreed to in your April 26, 2007, submission, and the immediate container (vial) submitted April 27, 2007. This determination is contingent upon information available to the Agency at this time (i.e., information in your application and the status of current good manufacturing practices of the facilities used in manufacturing and testing of the drug product) and is, therefore, subject to change on the basis of any new information that may come to our attention.

Your application contains a certification pursuant to section 505(b)(2)(A)(iv) (a "Paragraph IV certification") to U.S. Patent No. 6,488,027, which expires on March 8, 2019. You submitted this Paragraph IV certification to your application on March 12, 2007. The patent owner and NDA holder received notice of your certification on March 15, 2007. If the patent owner and NDA holder disagree with your assertion that the patent is invalid, unenforceable, or not infringed and file a patent infringement lawsuit within 45 days of receipt of your notice (i.e., by April 30, 2007), there will be a 30 month stay on approval of the application, which will have begun on March 15, 2007. Because that 45 day period has not yet expired, your application may only be tentatively approved.

If you are not sued as a result of your notice to the patent owner and NDA holder, please submit an amendment to this application containing that information and identifying changes, if any, in the conditions under which your product was tentatively approved. If you are sued in response to your notice, and there is a 30 month stay on approval of this NDA, at least 90-180 days prior to when you believe you will be eligible for final approval, or when requested, submit an amendment to this application identifying changes, if any, in the conditions under which your product was tentatively approved. This information should include an updated version of the content of labeling (21 CFR 314.50(l)) in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html , updated chemistry, manufacturing and controls data, and a safety update.

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 of your post-marketing study commitments in your submission dated January 25, and April 13, 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 twice daily 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 study 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."**

Any significant change in the conditions outlined in this NDA requires our review before final approval may be granted.

Before we issue a final approval letter, this NDA is not approved. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under section 301 of the Act.

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.

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

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
4/27/2007 04:50:03 PM