DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 16-126/S-025

Whitehall-Robins
Attention: Ms. Sharon Heddish
Five Giralda Farms
Madison, NJ 07940-0871

30 AUG 2001

Dear Ms. Heddish:

Please refer to your supplemental new drug application, (NDA) dated March 6, 2000, received on March 7, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Primatene Mist Inhalation Aerosol (epinephrine 5.5 mg/mL).

We acknowledge receipt of your amendments dated June 14, June 21, and November 10, 2000, and July 6, 2001, received March 15, June 23, and November 14, 2000, and July 9, 2001.

The supplemental new drug application provides for:

(1) revised storage condition specifications statement per approvable letter for S-015 dated February 27, 1998
(2) addition of a warning statement under the subheading, "When using this product" to alert consumer not to tamper with the container
(3) conformance with "Drug Facts" labeling in content and format in accordance with 21 CFR 201.66 (c) and (d)

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the draft labeling dated March 6, 2000, with the minor editorial revisions listed below. Accordingly, the application is approved effective on the date of this letter provided that the following changes are made to the labeling:

I. Outer Carton Label for ½ oz. with Mouthpiece, ½ oz. Refill and ¾ oz. Refill:

A. "Drug Facts" labeling - revise according to the attached prototype.

B. On all panels, where it reads “Epinephrine Inhalation Aerosol Bronchodilator,” relocate the word “Bronchodilator” to a separate line.

C. For the 3/4 fl. oz. Refill:

1. add "Drug Facts (continued)" to the bottom panel.
2. left panel, above “Questions or comments,?” add “Drug Facts (continued)” and a hairline underneath that heading.

II. Consumer information insert:

A. The title “Drug Facts” can remain as submitted or be removed. If the words “Drug Facts” are used, move the Directions for Use of the Mouthpiece outside the Drug Facts box, move the heavy black line from the right to the middle, extend the hair lines to within 2 spaces of either side of the box, and relocate the “Questions or comments” to an area immediately preceding the Directions for Use of the Mouthpiece. Add “Drug Facts (continued) if it is necessary to use the second column. The Directions for Use of the Mouthpiece could then remain at the right of the middle line. If the sponsor elects to remove the title “Drug Facts,” the Directions for Use of the Mouthpiece can remain anywhere on the Consumer Information Insert.

B. Same changes be made as on the carton labeling.

III. Container labels for ½ fl. oz. and ¾ fl. oz. sizes - same changes be made as on the carton labeling.

If final printed labeling (FPL) has not been printed, please revise the labeling as indicated above and submit FPL as an amendment to this supplement. If FPL has been printed, please revise the labeling as indicated above at the time of the next printing or within 180 days, whichever comes first, and submit as a new supplement to this application.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted draft labeling (carton and container labels, and Consumer Information Insert submitted March 6, 2000). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. For administrative purposes, this submission should be designated "FPL for approved NDA 16-126." Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of the labeling may be required.

If you have any questions, call Babette Merritt, Project Manager, at (301) 827-2222.

Sincerely,

Charles Ganley, M.D.
Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research