

NDA 20-120

Muro Pharmaceuticals, Inc
890 East Street
Tewksbury, Massachusetts 01876-1496

Attention: Joseph Celona
Director of Regulatory Affairs

Dear Mr. Celona:

Please refer to your new drug application (NDA) dated April 27, 1992, received April 28, 1992, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Tri-Nasal (triamcinolone acetonide) Nasal Spray.

We acknowledge receipt of your submissions dated May 20, and September 8, 1992, October 31, 1995, February 12, and 15, March 7, April 1, 9, 11, 24, and 29, May 7, June 4, July 1, 22, and 24, and August 2, 1996, April 14, and November 24, 1997, March 13, 1998, July 22, October 14, and 29, and November 22, 1999, January 20, and 31, and February 3, 2000. Your submission of July 22, 1999, constituted a complete response to our April 20, 1998, action letter.

This new drug application provides for the use of Tri-Nasal (triamcinolone acetonide) Nasal Spray for the treatment of nasal symptoms of seasonal and perennial allergic rhinitis in adults and children 12 years of age or older.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert, patient package insert, immediate container and carton labels submitted February 3, 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 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 20-120." Approval of this submission by FDA is not required before the labeling is used.

If you have any questions, call Mrs. Sandy Barnes, Project Manager, at (301) 827-1075.

Sincerely,

Robert J. Meyer, M.D.
Director
Division of Pulmonary and Allergy Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research