NDA 20-409/S-006

Dura Pharmaceuticals
5880 Pacific Center Blvd
San Diego, CA 92121-4204

27 MAR 2001

Attention: Terry L. Monk
Manager, Labeling Compliance

Dear Ms. Monk:

Please refer to your supplemental new drug application dated June 8, 1999, received June 9, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nasarel (flunisolide) Nasal Spray, 25 mcg.

This supplemental new drug application provides for revisions to the labeling for consistency with Nasalide (flunisolide) Nasal Spray, 25 mcg.

We have completed the review of this supplemental application 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 agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert, patient=s instructions for use, and immediate container and carton labels submitted June 8, 1999).

Please submit the 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. 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 supplement NDA 20-409/S-006." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under

21 CFR 314.80 and 314.81.

If you have any questions, call Sandy Barnes , Chief, Project Management Staff, 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