

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**75256\_S7**

**APPROVAL LETTER**

73-56  
ANDAs (See Attached List)

JUN 19 2002

Duramed Pharmaceuticals, Inc.  
A subsidiary of Barr Laboratories, Inc.  
Attention: Christine Mundkur  
2 Quaker Road  
P.O. Box 2900  
Pomona, NY 10970

Dear Madam:

This is in reference to your supplemental new drug applications dated March 28, 2002, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act, regarding your abbreviated new drug applications for the drug products on the attached list.

These supplemental applications, submitted as "Changes Being Effected in 30 Days," provide for alternative analytical testing laboratories.

We have completed the review of these supplemental applications and they are approved.

We remind you that you must comply with the requirements for an approved abbreviated new drug application described in 21 CFR 314.80-81.

The material submitted is being retained in our files.

Sincerely yours,

*ISI* *6/19/02*  
Rashmikant M. Patel, Ph.D.  
Director  
Division of Chemistry I  
Office of Generic Drugs  
Center for Drug Evaluation and Research