

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**75256\_S7**

**CHEMISTRY REVIEW(S)**

**Office of Generic Drugs**  
**Chemistry, Manufacturing, and Controls Review**

Review # 1: Global Supplement (See Attached List)

ANDA#: Global Supplement (see Attached List)

**Name and Address of Applicant:**

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

**Purpose of Supplement**

CBE-30: Alternate Analytical Testing Laboratory (PAC-ATLS) ✓

**Date(s) of Submission(s):**

Supplemental submission: 03-28-02 (received at OGD on 03-29-02)

**Pharmacological Category**

See Attachment

**Trade Name**

See Attachment

**Nonproprietary Name**

See Attachment

**Dosage Form**

Tablet

**Potency**

See Attachment

**Rx or OTC**

Rx

**Samples**

N/A

**Related IND/NDA/DMF**

N/A

**Sterilization**

N/A

**Remarks and Conclusion:** Approvable

This global supplement meets PAC-ATLS requirements.

**Recalls**

N/A

**Reviewer**

John D. Franolic, Ph.D.

**Date Completed**

6-11-2002

cc:                    ANDA See Attachment List  
                          Division File  
                          Field Copy

**Endorsements:**

HFD-623/John D. Franolic, Ph.D./6-11-2002 /

HFD-623/ D.Gill, Ph.D./6-12-2002

*Handwritten:* /S/ 6/17/02  
DSG:JN 6-17-02 ✓

F/T by : 6-12-2002

**Labeling:** N/A  
**Bioequivalency Status:** N/A  
**Establishment Inspection:** Acceptable, 04-08-2002

**Components/Composition/Manufacturing/Controls:** Satisfactory  
This global supplement provides for alternative analytical testing laboratories (~~PAC-ATLS~~) for the products listed on the attachment. The alternative analytical testing laboratories are located at:

Barr Laboratories, Inc.  
2150 Perrowville Road  
Forest, Virginia 24551

Barr Laboratories, Inc.  
2 Quaker Road, Bldg. #1  
Pomona, NY 10970

The firm will use the alternate analytical testing laboratories for performing microbiological and chemical testing on: (1) raw materials, i.e., drug substances and inactive ingredients, (2) in-process samples, and (3) finished product samples, i.e., release, validation, and stability. These alternate laboratories will test all samples by the approved analytical methods and/or the current official compendial or regulatory method.

*In support of this change, the firm provides the following criteria which meets the requirements of the CDER Guidance for Industry, PAC-ATLS (Postapproval Changes —Analytical Testing Laboratory Sites):*

1. The test methods approved in the affected applications and methods that have been implemented under 21 CFR 314.70(d) are being used at the VA and NY sites.
2. All post-approval commitments related to the test methods have been fulfilled.
3. The VA and NY testing facilities have the capability to perform the intended tests. Information to support capability of the VA and NY laboratories will be available for FDA investigator review.
4. The VA and NY testing facilities have had a satisfactory current good manufacturing practice (cGMP) inspection within the past 2 years (Accepted on 04-08-2002). During the period from Aug 20 through 24 and the 27 through 30, 2001, the Baltimore District inspected the Virginia site and found it to comply with cGMPs. The NY site was inspected on June 20 through 22, and the 25 through the 29, 2001, by the NY District and found it to comply with cGMPs. The applicant provides cGMP certification statement dated 3/28/02.

*The supplement meets the four criteria of PAC-ATLS and the information provided by the applicant is satisfactory. Thus the supplement is approvable.*

**Packaging:** N/A

**Stability:** N/A

**Order of Review:**

The application submission(s) covered by this review was taken in the date order or receipt:

Yes       X       No                     

**SPOT?**

Yes                      No       X      

If yes, complete a SPOT form.