



NDA 20186/S-026

**SUPPLEMENT APPROVAL**

Duramed Pharmaceuticals, Inc.  
Attention: Mr. Joseph A. Carrado  
One Belmont Avenue, 11th Floor  
Bala Cynwyd, PA 19004

Dear Mr. Carrado:

Please refer to your supplemental new drug application dated August 6, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Ziac (bisoprolol fumarate and hydrochlorothiazide) 2.5/6.25, 5/6.25 and 10/6.25 mg Tablets.

This "Changes Being Effected" supplemental new drug application provides changes to the ADVERSE REACTIONS section of the package insert, requested in our June 8, 2009 supplemental request letter.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, labeling text, which is identical to the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format submitted on August 6, 2009.

**LETTERS TO HEALTH CARE PROFESSIONALS**

If you issue a letter communicating important safety related information about this drug product (*i.e.*, a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch  
Food and Drug Administration  
5600 Fishers Lane, Room 12B05  
Rockville, MD 20857

**REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call:

Lori Wachter, RN, BSN  
Regulatory Health Project Manager  
(301) 796-3975

Sincerely,

*{See appended electronic signature page}*

Mary Ross Southworth, Pharm.D.  
Deputy Director for Safety  
Division of Cardiovascular and Renal Products  
Office of Drug Evaluation I  
Center for Drug Evaluation and Research

Enclosure  
Approved labeling text

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20186	SUPPL-26	DURAMED PHARMACEUTICA LS INC SUB BARR LABORATORIES INC	ZIAC

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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MARY R SOUTHWORTH  
11/06/2009