DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

SUPPLEMENT APPROVALS

NDA 19-982/S-014
NDA 20-186/S-023

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 applications (sNDAs) dated June 7, 2007, for Zebeta (bisoprolol fumarate) 5 and 10 mg tablets (NDA 19-982) and Ziac (bisoprolol fumarate and hydrochlorothiazide) 2.5/6.25, 5/6.25 and 10/6.25 mg tablets (NDA 20-186).

These supplemental new drug applications provide for the addition of the following statement to the PRECAUTIONS section of the labeling, in the Drug Interactions subsection in the label:

> Both digitalis glycosides and beta-blockers slow atrioventricular conduction and decrease heart rate. Concomitant use can increase the risk of bradycardia.

We have completed our review of these applications. They are approved, effective on the date of this letter, for use as recommended in the submitted labeling (package insert submitted on June 7, 2007).

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the submitted labeling. Upon receipt, we will transmit these versions to the National Library of Medicine for public dissemination. For administrative purposes, please designate these submissions, **"SPL for approved NDA 19-982/S-014"** and **"SPL for approved NDA 20-186/S-023".**

Marketing the products with FPL that is not identical to the approved labeling text may render the products misbranded and unapproved new drugs.

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
HFD-001, Suite 5100
5515 Security Lane
Rockville, MD 20852

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 Dan Brum, Pharm.D., Regulatory Project Manager, at (301)796-0578.

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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

/s/

Norman Stockbridge

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