ANDA 75-492 February 11, 2000

Keller & Heckman
Attention: John Dubeck
U.S. Agent for: Biovail Laboratories Incorporated
1001 G Street N.W., Suite 500 West
Washington D.C. 20001

Dear Sir:

This is in reference to your abbreviated new drug application dated October 30, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Diclofenac Sodium Extended-Release Tablets, 100 mg.

Reference is also made to your amendment dated November 19, 1999.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Diclofenac Sodium Extended-Release Tablets, 100 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Voltaren**7**-XR Tablets, 100 mg of Novartis Pharmaceutical Corporation).

We acknowledge that the following “interim” dissolution testing has been incorporated into your manufacturing controls and stability program. The "interim" dissolution test and tolerances are:

> The dissolution testing should be conducted in 900 mL of phosphate buffer, pH 7.5, at 37°C using USP Apparatus II(paddle) at 50 rpm. The test product should meet the following interim specifications:

Time(hours)	**% Dissolved**
[	]
[	]
[	]
[	]

The "interim" dissolution test and tolerances should be finalized by submitting dissolution data for the first three production size batches in a supplemental application. The supplemental application should be submitted as “Supplement-Changes Being Effected” when there are no revisions to the interim specifications or when the final specifications are tighter than the interim specifications. In all other instances the supplement should be submitted as a “Prior Approval Supplement”.

Under section 506 A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy that you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final
printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and

Research