DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-667/S-022

King Pharmaceuticals, Inc.
Attention: Dean R. Cirotta
Senior Director, Regulatory Affairs
501 Fifth Street
Bristol, TN 37620

27 SEP 2001

Dear Mr. Cirotta:

Please refer to your supplemental new drug application dated January 24, 2001, received January 26, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lorabid® (loracarbef for oral suspension, USP) for Oral Suspension, 100 mg/5 mL and 200 mg/5 mL. We note that this application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

This "Changes Being Effected" supplemental new drug application provides for the addition of the statement “Invert bottle and tap to loosen powder” to the **Directions for Mixing** section of the bottle label.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (immediate container labels submitted January 24, 2001). Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Beth Duvall-Miller, Regulatory Health Project Manager, at (301) 827-2125.

Sincerely,

Janice M. Soreth, M.D.
Acting Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research