DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 76-447/S-007

TEVA Pharmaceuticals USA
Attention: Philip Erickson, RPh
1090 Horsham Road
P.O. Box 1090
North Wales, PA 19454

Dear Sir:

This is in reference to your supplemental new drug applications dated April 4, 2007 submitted pursuant to 21 CFR 314.70(c) (Special Supplement - Changes Being Effected) regarding your abbreviated new drug applications for Fexofenadine Hydrochloride Tablets, 30 mg, 60 mg and 180 mg.

The supplemental application provides for revised package insert.

We have completed the review of this supplemental application and it is approved.

However, at the next time printing please revise the title on all labeling to read: Fexofenadine Hydrochloride Tablets, USP.

We remind you that you must comply with the requirements for an approved abbreviated new drug application described in 21 CFR 314.80-81.

The material submitted is being retained in our files.

Sincerely yours,

{See appended electronic signature page}

Wm Peter Rickman
Director
Division of Labeling and Program Support
Office of Generic Drugs
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/

John Grace
12/31/2007 11:10:08 AM
for Wm Peter Rickman