DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 65-162/S-021

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

Dear Sir:

This is in reference to your supplemental new drug application dated, January 15, 2009, submitted pursuant to 21 CFR 314.70 (c) Special Supplement - Changes Being Effected regarding your abbreviated new drug application for Amoxicillin and Clavulanate Potassium for Oral Suspension USP, 600 mg/42.9 mg per 5 mL.

The supplemental application provides for revised insert labeling reflecting revisions to the WARNINGS and PRECAUTIONS sections.

We have completed the review of this supplemental application and it is approved. However, further update your labeling as follows:

1. GENERAL COMMENTS

   a. Add the strength of both active ingredients when referring to Amoxicillin and Clavulanate Potassium.

   b. Increase the size of the asterisks.

Revised labeling with the above changes may be submitted in an annual report provided they are described in full. We refer you to 21 CFR 314.81(b)(2)(iii) for guidance.

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

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

/s/

Lillie Golson
3/5/2009 06:40:40 PM
Lillie Golson for Wm. Peter Rickman