CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 040445Orig1s003

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA: Attached List

Sandoz Inc.
Attention: Deborah A. Baldwin
4700 Sandoz Dr.
Wilson, NC 27893

Dear Madam:

This is in reference to your supplemental abbreviated new drug applications (sANDAs) dated December 19, 2012 submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act, regarding your abbreviated new drug applications (ANDAs) for : Attached List .

The sANDAs, submitted as "Supplement - Changes Being Effected" provide for:

Revision of specification of Sodium Starch Glycolate NF in order to comply with the official compendium

We have completed the review of these sANDAs and they are approved.

We remind you that you must comply with the requirements for the approved ANDAs described in 21 CFR 314.80-81.

The material submitted is being retained in our files.

Sincerely yours,

{See appended electronic signature page}

Paul Schwartz, Ph.D.
Supervisory Chemist
Office of Generic Drugs
Center for Drug Evaluation and Research

Group Supplement List

Product Name	**Strength(s)**	**ANDA#**
Etodolac Tablets USP	400 mg and 500 mg	074903/S019
Fluvoxamine Maleate Tablets USP	25 mg, 50 mg and 100 mg	075888/S029
Hydroxyzine Pamoate Capsules USP	25 mg	087479/S033
Hydroxyzine Pamoate Capsules USP	50 mg	086183/S034
Labetalol Hydrochloride Tablets USP	100 mg, 200 mg and 300 mg	075113/S023
Metaxalone Tablets	800 mg	040445/S003
Sotalol Hydrochloride Tablets USP	80 mg, 120 mg, 160 mg and 240 mg	075366/S022

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

/s/

PAUL SCHWARTZ
01/10/2013