DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 075274/S-010

Elite Laboratories, Inc.
Attention: Mimi Park
165 Ludlow Avenue
Northvale, NJ 07647

Dear Madam:

This is in reference to your supplemental new drug application dated October 6, 2011 submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act, regarding your abbreviated new drug application for Naltrexone Hydrochloride Tablets USP, 50 mg.

Reference is also made to your quality minor amendment dated April 10, 2012.

The supplemental application submitted as, "Supplement – Changes Being Effected in 30 Days," provides for:

- Elite Laboratories, Inc. facility located at 165 Ludlow Avenue, Northvale, NJ 07647 as the manufacturing site for Naltrexone Hydrochloride Tablets USP, 50 mg.
- Epic Pharma, LLC facility located at 227-15 North Conduit Avenue, Laurelton, NY 11413 as the packaging site for Naltrexone Hydrochloride Tablets USP, 50 mg.
- Concomitant labeling revisions

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

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}

Glen J. Smith
Director
Division of Chemistry II
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/

GLEN J SMITH
01/31/2013