DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

sANDA 091422/S-006

APPROVAL

Actavis Elizabeth LLC
Attention: Janak Jadeja
Director, Regulatory Affairs
200 Elmora Street
Elizabeth, NJ 07207

Dear Sir:

Please refer to your Supplemental Abbreviated New Drug Application (sANDA) dated and received May 31, 2013, submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act, regarding your abbreviated new drug application (ANDA) for Buprenorphine Hydrochloride and Naloxone Hydrochloride Dihydrate Sublingual Tablets, Eq. 2 mg/0.5 mg and 8 mg/2 mg Base.

We acknowledge receipt of your amendment dated February 28, 2014.

The supplemental ANDA, submitted as a "Prior Approval Supplement," provides for the following changes:

- (b) (4) the stability limit for total degradants related to naloxone from NMT (b) (4) to NMT (b) (4).
- Monitoring of the specified identified degradant, (b) (4), with a control limit of NMT (b) (4) at final product release and at NMT (b) (4) during shelf-life.
- A new packaging configuration; unit dose blister pack of 30 tablets for Buprenorphine Hydrochloride and Naloxone Hydrochloride Dihydrate Sublingual Tablets.
- (b) (4)

We have completed our review of this sANDA, as amended, and it is approved. Please note along with this approval, the Labeling Review Branch recommends at the time of your next printing, please revise the established name for this drug product to be "Buprenorphine and

Naloxone Sublingual Tablets" throughout your labels and labeling. Revise the established name on the blister labels to read "… Tablet" rather than "… Tablets".

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

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1 of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the Federal Register notice announcing facility fee amounts. All finished dosage forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

The material submitted is being retained in our files.

Sincerely yours,

{See appended electronic signature page}

Kathleen Uhl, M.D.
Acting Director
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/

PAUL SCHWARTZ
05/15/2014
Signed for K. Uhl