DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

sANDA 203136/S-003

APPROVAL

Amneal Pharmaceuticals
Attention: Alpesh Patel
Vice President, Global Regulatory Affairs
85 Adams Avenue
Hauppauge, NY 11788

Dear Sir:

Please refer to your Supplemental Abbreviated New Drug Application (sANDA) dated May 29, 2013, received May 30, 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, 2 mg/0.5 mg and 8 mg/2 mg.

The supplemental ANDA, submitted as a "Prior Approval Supplement," provides for the use of a child resistant blister packaging configuration for both tablet strengths (2 mg/0.5 mg and 8 mg/2 mg).

We have completed our review of this sANDA and it is approved.

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/

NILES N RON on behalf of PAUL SCHWARTZ
04/18/2014