DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDAs 071972
071973
071974

CONSOLIDATION APPROVAL

Impax Laboratories, Inc.
30831 Huntwood Avenue
Hayward, CA 94544
Attention: Billie Wiltison

RECEIVED
SHz 18May18

Dear Billie Wiltison,

This is in reference to the correspondences dated January 24, 2017 regarding your Abbreviated New Drug Applications (ANDAs) submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act for Propranolol Hydrochloride Tablets USP, 10 mg (ANDA 071972), Propranolol Hydrochloride Tablets USP, 20 mg (ANDA 071973), and Propranolol Hydrochloride Tablets USP, 40 mg (ANDA 071974).

These correspondences request the following change:

> Consolidation of multiple approved ANDAs into a single application in compliance with the CDER guidance entitled: "Variations in Drug Products that may be included in a Single ANDA."

You have requested consolidation of ANDAs 071973 and 071974 into **ANDA 071972**. We have completed the review of these correspondences and your request is approved.

We remind you that you must comply with the requirements for the approved abbreviated new drug application described in 21 CFR 314.80-81.

ANDAs 071972
071973
071974

If you have any questions, contact Kathleen Melendez, ANDA Consolidation Coordinator, at Kathleen.Melendez@fda.hhs.gov[1] or 240-402-2358.

Sincerely,

Kathleen M. Melendez -S

Digitally signed by Kathleen M. Melendez -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2001757355, cn=Kathleen M. Melendez -S
Date: 2018.05.14 12:29:19 -04'00'

Kathleen Melendez, Pharmacist
Division of Filing Review
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

[1] Secure email between CDER and applicants may be useful for informal communications when confidential information may be included in the message (for example, trade secrets or patient information). If you have not already established secure email with FDA and would like to set it up, send an email request to SecureEmail@fda.hhs.gov. Please note that secure email may not be used for formal regulatory submissions to applications.

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/s/

ROBYN J CHOI
05/14/2018