



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDAs 071880
071881

**CONSOLIDATION
APPROVAL**

Heritage Pharmaceuticals Inc.
One Tower Center Blvd., Suite 1700
East Brunswick, NJ 08816
Attention: Pankaj Dave

Dear Pankaj Dave,

This is in reference to the correspondences dated February 16, 2017 and February 1, 2018 regarding your Abbreviated New Drug Applications (ANDAs) submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act for Verapamil Hydrochloride Tablets USP, 40 mg and 120 mg (ANDA 071881) and Verapamil Hydrochloride Tablets USP, 80 mg (ANDA 071880).

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 ANDA 071880 into **ANDA 071881**. 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.

If you have any questions, contact Kathleen Melendez, ANDA Consolidation Coordinator, at Kathleen.Melendez@fda.hhs.gov¹ 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: 2018.02.05 08:08:01 -05'00'

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
02/20/2018