DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

ANDA 040282/S-013

APPROVAL

Mylan Pharmaceuticals Inc.
Attention: Joseph J. Sobecki
Vice President, Regulatory Affairs
781 Chestnut Ridge Road
P.O. Box 4310
Morgantown, WV 26504-4310

Dear Sir:

Please refer to your Supplemental Abbreviated New Drug Application (sANDA) dated October 18, 2011, received October 18, 2011, submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act, regarding your abbreviated new drug application (ANDA) for Digitek® Tablets (Digoxin Tablets, USP), 0.125 mg and 0.25 mg.

We acknowledge receipt of your amendments dated January 27, 2012; February 18, and November 8, 2013, and April 14, and May 19, 2014.

The sANDA, submitted as a "Prior Approval Supplement," provides for:

S-013 Mylan LLC (Caguas, Puerto Rico) as an alternate manufacturing, packaging and analytical testing site for Digitek Tablets (Digoxin Tablets USP, 0.125 mg and 0.25 mg; and

Mylan Pharmaceuticals Inc. (Morgantown WV) as an alternate analytical testing site for the components of the finished drug product.

We have completed our review of this sANDA, as amended, 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}

CAPT Jason J.Y. Woo, M.D., M.P.H.
Acting Director, Office of Regulatory Operations
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/

ROBERT L WEST

09/03/2014

Associate Director for Review Quality, for
Jason Woo, M.D., M.P.H.