



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 75-109

Amneal Pharmaceuticals
Attention: Chintu Patel
Chief Executive Officer
209 McLean Blvd.
Paterson, NJ 07504

Dear Sir:

We acknowledge receipt of your communication dated October 18, 2007, submitted as required by the provisions of Regulation 21 CFR 314.72(a) and Section 505(k) of the Federal Food, Drug and Cosmetic Act for the abbreviated new drug application (ANDA) for Guanfacine Hydrochloride Tablets, 1 mg (base) and 2 mg (base).

Your letter details the transfer of ownership of the ANDA from Genpharm Inc. to Amneal Pharmaceuticals.

Pursuant to 21 CFR 314.72(b), the new owner shall advise FDA about any change in the conditions of the approved application.

The material submitted is being retained as part of your application.

Sincerely yours,

{See appended electronic signature page}

William P. Rickman
Director
Division of Labeling and Program Support
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/

Timothy W. Ames
5/12/2008 04:20:57 PM
Signing for Wm. Peter Rickman