

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPROVAL PACKAGE FOR:**

**APPLICATION NUMBER  
19-032/S-016 and S-017**

**Correspondence**



NDA 19-032/S-017

A.H. Robins  
Attention: Ms. Mary Alice Dankulich  
170 Radnor Chester Road  
St. Davids, PA 19087

Dear Ms. Dankulich:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Tenex (guanfacine HCl) Tablets

NDA Number: 19-032

Supplement Number: S-017

Date of Supplement: November 20, 2000

Date of Receipt: November 21, 2000

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on January 20, 2001 in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

Center for Drug Evaluation and Research  
Division of Cardio-Renal Drug Products  
Office of Drug Evaluation I  
Attention: Document Control Room, HFD-110  
5600 Fishers Lane  
Rockville, MD 20857

Sincerely,

A handwritten signature in black ink, appearing to be "N. Morgenstern", written over a horizontal line.

Natalia A. Morgenstern  
Chief, Project Management Staff  
Division of Cardio-Renal Drug Products, HFD-110  
Office of Drug Evaluation I  
Center for Drug Evaluation and Research

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cc:

Original NDA 19-032/017

HFD-110/Div. Files

HFD-110/CSO/John Guzman

Filename: G:\PM Folder\NDA ltrs\19032s17.doc

SUPPLEMENT ACKNOWLEDGEMENT

/s/

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Natalia Morgenstern  
12/14/00 05:43:12 PM