Good Pharmaceuticals
202 New Drug Road
Pharmaceutical, Maryland 00000

May 1, 2001

Food and Drug Administration
Center for Drug Evaluation and Research
Division
Attention: Division Director
Woodmont II
1451 Rockville Pike
Rockville, Maryland 20852

Dear Dr._____

Reference is made to INDxxxxx and NDA 31025.

Good Pharmaceuticals is submitting this New Drug Application for Blockbuster Drug. This initial application contains all requisite information to support approval of Blockbuster Drug for depression.

The information for this NDA is submitted in 5 volumes in the format of the Common Technical Document. The submission consists of one archival copy and the review copies. Each review copy includes a copy of Module 1 and Module 2.

There is one review copy of quality (Module 3), one for safety (Module 4) and three copies (one for bio pharmaceutic reviewers, one for the statistician, and one for the clinical reviewer) efficacy (Module 5).

Good Pharmaceuticals certifies that it submitted a field copy of the application to the local field office.

If you have any questions regarding this application, please contact me at 410-52x-xxxx.

Sincerely,

Allswell Titer,
Director, Regulatory Affairs
Good Pharmaceuticals