

**Exhibit 3**



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Gary Buehler, Director  
Office of Generic Drugs  
Food and Drug Administration  
Document Control Room  
Metro Park North II  
7500 Standish Place, Room 150  
Rockville, Maryland 20855-2773

**NEW CORRESPONDENCE**

ANDA # 76-228  
RISPERIDONE TABLETS, 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg and 4 mg  
NEW CORRESPONDENCE

Dear Mr. Buehler:

We submit herewith a new correspondence to the above-referenced original abbreviated new drug application in response to an October 12, 2001 telephone conversation between Ms. Emily Thomas (Project Manager FDA) and Philip Erickson of TEVA Pharmaceuticals USA. Specifically, Ms. Thomas has requested the following additional information:

- 1) Reference listed drug labels for Risperidone Tablets, 0.25 mg, 0.5 mg, 2 mg and 3 mg. Please find enclosed copies of the labeling for Risperdal® Tablets, 0.25 mg, 0.5 mg, 2 mg and 3 mg. (*Attachment 1*)
- 2) Revised patent certification. U.S. Patent 5,158,952 with an expiration of October 27, 2009 has been officially delisted from the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book), therefore only U.S. Patent 4,804,663 with an expiration of December 29, 2007 remains. Please find enclosed a patent certification revised accordingly. (*Attachment 2*)

The information presented herein represents, in our opinion, a complete response to the questions presented in the October 12, 2001 telephone conversation. This information is submitted for your continued review and acceptance of ANDA # 76-228. If there are any further questions, please do not hesitate to contact me at (215) 591-3141 or facsimile at (215) 591-8812.

Sincerely,

PE/cw  
Enclosures