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RESEARCH**

APPLICATION NUMBER:
75411

CORRESPONDENCE

April 14, 2000

Office of Generic Drugs
CDER, FDA
MPN II, HFD-600
7500 Standish Place
Rockville, MD 20855

ORIG AMENDMENT
N/A

LABELING AMENDMENT

RE: ANDA 75-411 and ANDA 75-412
Timolol Maleate Ophthalmic Solution USP,
0.25% and 0.5%

To Whom It May Concern:

Apotex Corp., as the U.S. agent for Novex Pharma of Ontario, Canada, is hereby forwarding a response to the telephone call on April 06, 2000 between Marcy Macdonald of Apotex Corp. and Lily Golson, OGD FDA. An original and a duplicate are being submitted.

If you have any further questions, please do not hesitate to contact me.

Sincerely,

Marcy Macdonald

Marcy Macdonald
Associate Director
Regulatory Affairs
Ext. 223



March 31, 2000

Office of Generic Drugs
CDER, FDA
MPN II, HFD-600
7500 Standish Place
Rockville, MD 20855

ORIGINAL AMENDMENT

LABELING AMENDMENT

RE: ANDA 75-411 and ANDA 75-412
Timolol Maleate Ophthalmic Solution USP 0.25% and 0.5%

To Whom It May Concern:

Apotex Corp., as the U.S. agent for Novex Pharma of Ontario, Canada, is hereby forwarding a response to the telephone call on March 28, 2000. An original and a duplicate are being submitted.

If you have any further questions, please do not hesitate to contact me.

Sincerely,

Marcy Macdonald

Marcy Macdonald
Associate Director
Regulatory Affairs
Ext. 223





50 LAKEVIEW PARKWAY • SUITE 127 • VERNON HILLS • ILLINOIS 60061 • TEL (847) 573-9999 • FAX (847) 573-1001

August 4, 2000

Office of Generic Drugs
CDER, FDA
MPN II, HFD-600
7500 Standish Place
Rockville, MD 20855

ORIG AMENDMENT

N/AM

MINOR AMENDMENT

RE: ANDA 75-411
Timolol Maleate Ophthalmic Solution USP,
0.25%

To Whom It May Concern:

Apotex Corp., as the U.S. agent for Novex Pharma of Ontario, Canada, is hereby forwarding a response to the minor deficiency letter dated July 10, 2000. An original, a duplicate and a field copy are being submitted.

If you have any further questions, please do not hesitate to contact me.

Sincerely,

Marcy Macdonald

Marcy Macdonald
Associate Director
Regulatory Affairs
Ext. 223

