



Food and Drug Administration
Silver Spring, MD 20993

April 4, 2023

Jeff Watson
President and Chief Executive Officer
Apotex Inc.
150 Signet Drive
Toronto, ON M9L 1T9
(416) 749-9300

Dear Mr. Watson,

The U.S. Food and Drug Administration (FDA or the Agency) is pleased to announce that Apotex Corporation (Apotex) has been selected to receive a Drug Shortage Assistance Award for its role in preventing or alleviating a drug shortage.

Apotex is being recognized for its efforts related to alleviating a shortage of Varenicline Tablets, 0.5 mg and 1 mg, including temporary importation of their product and ultimately submitting and obtaining approval of an abbreviated new drug application (ANDA 201962).

FDA established this award program to recognize companies for making a substantial contribution to preventing or alleviating a drug shortage. FDA hopes this award serves as an incentive for other companies to assist in addressing drug shortages, as Apotex has done.

The intent of the award program is to recognize manufacturers or companies that assist FDA in addressing a drug shortage for their commitment to public health and quality manufacturing, a key component of the Strategic Plan for Preventing and Mitigating Drug Shortages. More information on the strategic plan can be found on FDA's drug shortages web page (<http://www.fda.gov/drugs/drugsafety/drugshortages/default.htm>).

FDA thanks Apotex Corp. for working to mitigate the shortage of Varenicline Tablets, 0.5 mg and 1 mg. The enclosed press release/web statement template is provided to assist you in publicizing your award from FDA.

Sincerely,

Douglas Throckmorton, M.D.
Deputy Center Director for Regulatory Programs,
FDA, Center for Drug Evaluation and Research

Enclosure(s):
Certificate
Optional Press Release/Web Statement Template

cc: Andrew McNicoll, SVP, Head of Quality and Compliance, Apotex Corp.
Kiran Krishnan, SVP, Regulatory Affairs