NDA 020936/S-065

SUPPLEMENT APPROVAL

Apotex Technologies Inc.
c/o Apotex Corp.
Attention: Kiran Krishnan, SVP, GRA
2400 North Commerce Parkway
Suite 400
Weston, FL 33326

Dear Kiran Krishnan:

Please refer to your Supplemental New Drug Application (sNDA) dated and received August 23, 2023, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Paxil CR (paroxetine) extended-release tablet.

This "Changes Being Effected" supplemental new drug application provides for incorporation of changes to the drug product description in the US Package Insert (section 3, Dosage Forms and Strengths) due to a change in tablet appearance and to correspond to the labeling text approved for this drug product in NDA 020936/S-050 on September 18, 2017, in which the drug product appearance and description was changed.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

RECOMMENDATIONS

The following are recommendations for future labeling update considerations to minimize the risk of medication error:

	IDENTIFIED ISSUE	RATIONALE FOR CONCERN	RECOMMENDATION
General Comment			
1.	Apotex proposes to revert to a previous storage statement in the Prescribing Information. However, it is not clear that this storage statement is on the container labels.	The storage statement in the Prescribing Information should be consistent with the storage statement on the container labels. Inconsistency in the storage statements may lead to confusion.	Container labels were not submitted with this supplement. The storage statement on the container labels should be consistent with the storage statement in the Prescribing Information.
Full Prescribing Information – Section 16 How Supplied/Storage and Handling			
1.	There is a dash following the 12.5 mg and 25 mg strengths (i.e., 12.5-mg yellow tablets and 25-mg pink tablets).	The dash impairs the readability of the strength.	Delete the dashes.
2.	The storage statement reads as follows: "Store at or below 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30° (59° to 86°F) [see USP Controlled Room Temperature]." The first temperature numerical unit is missing the degree symbol and the first "excursions permitted..." numerical range is missing the unit of measure.	The storage statement lacks completeness and this may lead to confusion.	Consider revising the storage statement as follows: "Store at or below 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature]."

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the prescribing information, and Medication Guide) with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled *SPL Standard for Content of Labeling Technical Qs and As* at

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Teshara G. Bouie, Senior Regulatory Business Process Manager, at (301) 796 - 1649.

Sincerely,

{See appended electronic signature page}

David Lewis, Ph.D.
on behalf of
Gurpreet Gill-Sangha, Ph.D.
Supervisor
Division of Product Quality Assessment II
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure:
Content of Labeling

David Lewis

Digitally signed by David Lewis
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