Vivus tried again with FDA for weight-loss drug

The Associated Press

MOUNTAIN VIEW, Calif. (AP) — Drug developer Vivus Inc. has resubmitted an application for its potential weight-loss drug Qnexa to the Food and Drug Administration.

The Mountain View, Calif., company said Monday the resubmission follows an agreement on filing strategy that it reached last month with representatives of the FDA's Endocrine and Metabolic Division.

Qnexa has been touted by many experts as the most promising weight-loss drug in more than a decade. But the FDA declined to approve it last year and had asked Vivus Inc. to look into the risk of birth defects in women who use Qnexa ingredient topiramate as a migraine treatment.

The company met with the FDA earlier this year to discuss studying existing electronic health care databases to assess birth defects in the children of women who were exposed to topiramate during pregnancy. Vivus has said it agreed with the FDA on the study's design, goals and eligibility criteria.

The resubmission seeks approval for the treatment of obesity for obese or overweight patients with conditions like hypertension or type 2 diabetes. Proposed labeling for the drug includes a contraindication for women who could potentially become pregnant.