Insulet via UPI

The Omnipod 5 integrates with a continuous glucose monitor to manage blood sugar with no multiple daily injections or finger-sticks and can be controlled by a smartphone.

FDA approves the first automated insulin delivery system for people 18 and older with Type 2 diabetes

BY ALLEN CONE
UPI

The Food and Drug Administration on Monday approved Insulet's Omnipod 5 automated insulin delivery system for people with Type 2 diabetes.

In 2022, the FDA signed off on the system for Type 1 diabetes for those 2 years and older.

The expanded use is for those 18 and older with Type 2 diabetes.

The interoperable automated glycemic controller is software that automatically adjusts insulin delivery to a person with diabetes by connecting to an alternative controller-enabled insulin pump and integrated continuous glucose monitor.

"The FDA has long worked with the diabetes community to ensure access to additional options and flexibilities for diabetes management," said Dr. Michelle Tarver, the acting director of the FDA's Center for Devices and Radiological Health. "The FDA is committed to advancing new-device innovation that can improve the health and quality of life for people living with chronic diseases that require day-to-day maintenance like diabetes."

Insulet, a public company, applauded the approval.

"Today's announcement represents a significant milestone in providing easy-to-use, patient-centric technology for the treatment of Type 2 diabetes," Insulet CEO Jim Hollingshead said in a news release.

In 2000, Intuit founder John Brooks III, whose son, Rob, was diagnosed with Type 1 diabetes at age 3, developed a small pump device worn directly on the body rather than using tubing.

In 2003, the FDA first cleared an Omnipod Insulin Management System that didn't include a continuous monitoring system.

With the new system, a wearable, tubeless product provides up to three days of nonstop insulin delivery without the need to handle a needle. The Omnipod 5 integrates with a continuous glucose monitor to manage blood sugar with no multiple daily injections or finger-sticks and can be controlled by a compatible smartphone or by a controller.

Insulin options for people with Type 2 diabetes were limited to methods such as injection via syringe, an insulin pen or an insulin pump. These require patients to self-administer insulin one or more times a day and check blood glucose frequently to achieve the best results.

"Today's clearance provides a new option that can automate many of these manual tasks, potentially reducing the burden of living with this chronic disease," the FDA said in the news release.

The FDA reviewed data from a 13-week clinical study of 289 individuals 18 years and older with Type 2 diabetes. The study included a range of racial and ethnic backgrounds, ages, and education and income levels.

The study showed that volunteers' blood sugar control improved from before the study, and these improvements were seen across all demographic groups. In addition, there were no complications or serious adverse events related to the use of the SmartAdjust technology.

Adverse events were generally mild to moderate and included hyperglycemia, or high blood sugar; hypoglycemia, or low blood sugar, and skin irritation.

In the United States, 11.6% of the population, about 38.4 million people, have diabetes diagnoses, according to the Centers for Disease Control and Prevention. It is a condition in which the body does not make enough of or does not properly use the blood glucose-regulating hormone insulin.

An estimated 97.6 million people 18 years or older had prediabetes in 2021. About 90% to 95% are Type 2, according to the CDC.

In Type 1, the pancreas does not make insulin, because the body's immune system attacks the islet cells in the pancreas. In Type 2, the pancreas makes less insulin than it used to, and the body becomes resistant to insulin.

Cholesterol changes during menopause can spur heart disease, study indicates

BY DENNIS THOMPSON
HealthDay News
UPI

During menopause, a woman's blood cholesterol changes in a way that could harm her heart health, a new study warns.

An increase in "bad" LDL cholesterol and a decrease in "good" HDL cholesterol occurs during menopause, according to research to be presented Monday at the European Society of Cardiology's annual meeting in London.

"Taken together, these changes suggest that menopause is associated with a transition to a higher-risk lipoprotein [cholesterol] profile that could be more likely to cause cardiovascular disease, such as coronary artery disease," said researcher Dr. Stephanie Moreno, a resident with the University of Texas Southwestern Medical Center in Dallas.

Heart disease is the biggest killer of women, causing 40% of all deaths in females, researchers noted.

Women tend to develop heart disease about 10 years later than men, with their risk rising dramatically after menopause.

But until now, it has not been clear why a woman's risk of heart disease accelerates after menopause.

For this study, researchers analyzed blood cholesterol levels in 1,246 women and 1,346 men participating in a long-term heart health study.

Of the women, 35% were premenopausal, 24% were menopausal and 41% were postmenopausal.

Over an average follow-up time of seven years, all three groups of women experienced an increase in "bad" LDL cholesterol.

However, the greatest percentage change in LDL cholesterol occurred between menopause and postmenopause, with levels rising 8.3%, researchers found. Further, postmenopausal women also experienced a 4.8% decline in their levels of "good" HDL cholesterol.

In comparison with men, menopausal women had a 213% rise in "bad" LDL cholesterol, results showed.

"We found that menopause is associated with adverse changes in lipoprotein profiles, with the most pronounced changes found to be in increases in 'bad' LDL-particles," Moreno said in a news release.

Because these findings were presented at a medical meeting, they should be considered preliminary until published in a peer-reviewed journal.

PUBLIC HEARING

The Miami-Dade County Transportation Disadvantaged (TD) Local Coordinating Board (LCB) will hold a Public Hearing on Wednesday, September 11, 2024, at 10:00 AM in the Miami-Dade Transportation Planning Organization Offices located at 150 West Flagler Street, Suite 1924 Miami, FL 33130 for the purpose of receiving input regarding unmet needs or any other area(s) that relate to the local transportation services for the TD community. All interested parties are invited to attend.

For further information, please contact the LCB Coordinator Malcolm Moyse Jr. at (305) 375-4507, or Malcolm.MoyseJr@MiamiDade.gov.

It is the policy of the Miami-Dade TPO to comply with all requirements of the Americans with Disabilities Act. For assistance, please call 305-375-1888 at least five business days in advance.

CITY OF DORAL
NOTICE OF PUBLIC HEARING

All residents, property owners and other interested parties are hereby notified of a **COUNCIL MEETING** on **September 11, 2024 beginning at 6:00 PM** to consider a modification to the Midtown Doral Planned Unit Development (PUD) Phases IV, V, and VI, Master Development Agreement (MDA) and Pattern Book. The City Council will consider this item for **SECOND READING**. The meeting will be held at the **City of Doral, Government Center, Council Chambers located at 8401 NW 53rd Terrace, Doral, Florida, 33166.**

The City of Doral proposes to adopt the following Ordinance:

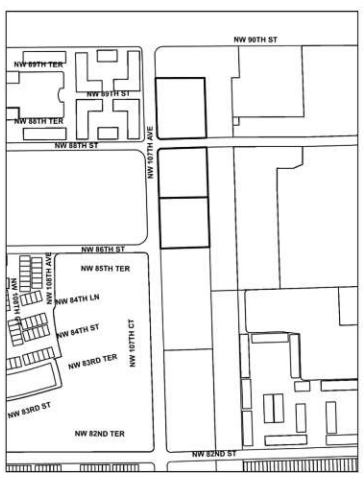
ORDINANCE No. 2024-24

AN ORDINANCE OF THE MAYOR AND THE CITY COUNCIL OF THE CITY OF DORAL, FLORIDA, APPROVING A MODIFICATION TO THE MIDTOWN DORAL PLANNED UNIT DEVELOPMENT (PUD) PHASES IV, V, AND VI MASTER DEVELOPMENT AGREEMENT AND PATTERN BOOK TO INCREASE APPROVED RESIDENTIAL UNITS FROM 253 TO 552, REDUCE COMMERCIAL GROSS LEASEABLE AREA FROM 96,875 SQUARE FEET TO 22,740 SQUARE FEET; AND REMOVE 75,000 SQUARE FEET OF NET LEASEABLE AREA OF OFFICE USE FOR AN EFFECTIVE DATE

HEARING NO.: 24-09-DOR-03
APPLICANT: MTD Unit 3 503, LLC/ DelCop Group LLC (the "Applicant")
PROJECT NAME: Midtown PUD Modification Phase IV, V, and VI
PROPERTY OWNER: MTD Unit 3 503, LLC / DelCop Group, LLC
LOCATION: Generally located east of NW 107 Avenue and situated to the north and south of NW 88 Street
FOLIO NUMBER: 35-3008-000-0041, 35-3008-000-0048, and 35-3008-000-0051
SIZE OF PROPERTY: ±7.2 acres
FUTURE LAND USE CATEGORY: Community Mixed Use and Regional Activity Center
ZONING DISTRICT: Planned Unit Development (PUD)
REQUEST: : The Applicant is requesting to modify the development program for Phases IV, V, and VI of the Midtown Doral Planned Unit Development; Phase IV consisting of a maximum of 146 dwelling units, Phase V with a maximum of 203 dwelling units and 11,370 square feet of gross leasable area of commercial use, and Phase VI with a maximum of 203 dwelling units and 11,370 square feet of gross leasable area of commercial use.

Inquiries regarding the item may be directed to the Planning and Zoning Department at 305-59-DORAL. The application file may be examined at the City of Doral Planning and Zoning Department located at 8401 NW 53 Terrace, Doral, FL 33166.

Location Map



Pursuant to Section 286.0105, Florida Statutes If a person decides to appeal any decisions made by the City Council with respect to any matter considered at such meeting or hearing, they will need a record of the proceedings and, for such purpose, may need to ensure that a verbatim record of the proceedings is made, which record includes the testimony and evidence upon which the appeal is to be based. This notice does not constitute consent by the City for introduction or admission of otherwise inadmissible or irrelevant evidence, nor does it authorize challenges or appeals not otherwise allowed by law. In accordance with the Americans with Disabilities Act, any person who are disabled and who need special accommodations to participate in this meeting because of that disability should contact the Planning and Zoning Department at 305-59-DORAL no later than three (3) business days prior to the proceeding.

Connie Diaz, MMC
City Clerk
City of Doral

CITY OF DORAL
NOTICE OF PUBLIC HEARING

All residents, property owners and other interested parties are hereby notified of a **COUNCIL MEETING** on **September 11, 2024 beginning at 6:00 PM** to consider an amendment to the City's Official Zoning Map. The City Council will consider this item for **SECOND READING**. The meeting will be held at the **City of Doral, Government Center, Council Chambers located at 8401 NW 53rd Terrace, Doral, Florida, 33166.**

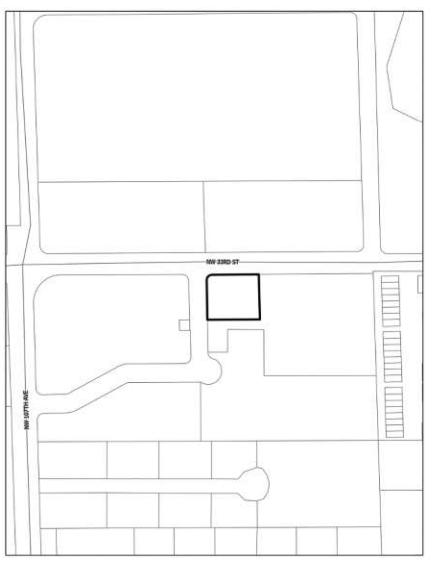
The City of Doral proposes to adopt the following Ordinance:

ORDINANCE No. 2024-18

AN ORDINANCE OF THE MAYOR AND THE CITY COUNCIL OF THE CITY OF DORAL, FLORIDA, APPROVING AN AMENDMENT TO THE CITY'S OFFICIAL ZONING MAP FROM INDUSTRIAL DISTRICT (I) TO INDUSTRIAL COMMERCIAL DISTRICT (IC) FOR A ±0.028-ACRE PARCEL OF LAND LOCATED AT 10450 NORTHWEST 33 STREET; PROVIDING FOR SEVERABILITY; PROVIDING FOR CONFLICTS; AND PROVIDING FOR AN EFFECTIVE DATE

HEARING NO.: 24-09-DOR-02
APPLICANT: Harborgenix, LLC (the "Applicant")
PROJECT NAME: Harborgenix, LLC Rezoning
PROPERTY OWNER: Harborgenix, LLC
LOCATION: 10450 NW 33 Street, Doral, FL
FOLIO NUMBER: 35-3029-118-0001
SIZE OF PROPERTY: ±0.028 acres
FUTURE LAND USE MAP CATEGORY: Industrial
ZONING DISTRICT: Industrial (I)
REQUEST: The Applicant is requesting a zoning map amendment from Industrial (I) to Industrial Commercial (IC) for the property located at 10450 NW 33 Street.

Location Map



Inquiries regarding the item may be directed to the Planning and Zoning Department at 305-59-DORAL. The application file may be examined at the City of Doral Planning and Zoning Department located at 8401 NW 53 Terrace, Doral, FL 33166.

Pursuant to Section 286.0105, Florida Statutes If a person decides to appeal any decisions made by the City Council with respect to any matter considered at such meeting or hearing, they will need a record of the proceedings and, for such purpose, may need to ensure that a verbatim record of the proceedings is made, which record includes the testimony and evidence upon which the appeal is to be based. This notice does not constitute consent by the City for introduction or admission of otherwise inadmissible or irrelevant evidence, nor does it authorize challenges or appeals not otherwise allowed by law. In accordance with the Americans with Disabilities Act, any person who are disabled and who need special accommodations to participate in this meeting because of that disability should contact the Planning and Zoning Department at 305-59-DORAL no later than three (3) business days prior to the proceeding.

Connie Diaz, MMC
City Clerk
City of Doral