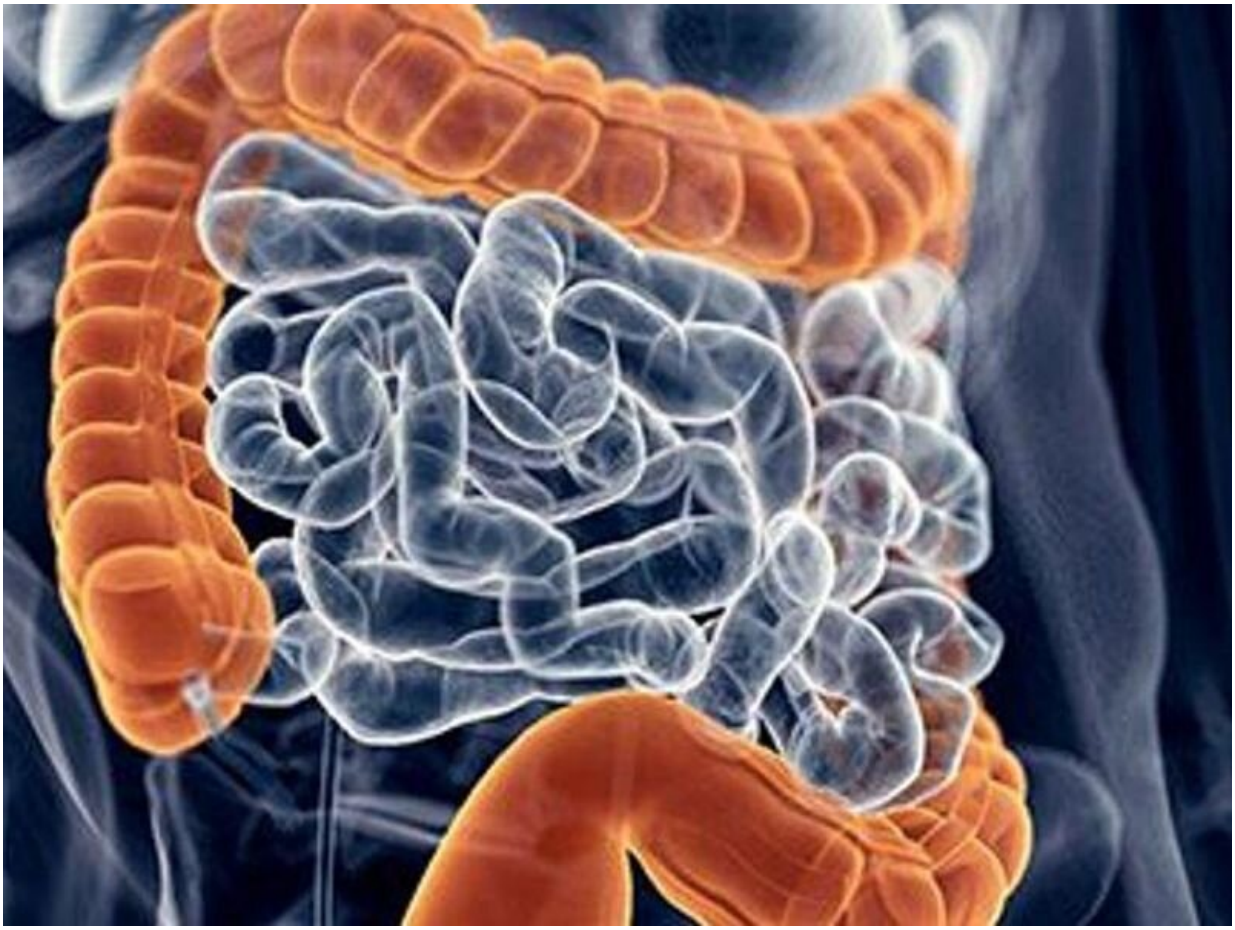
FDA approves first pill for fecal transplant therapy

April 27 2023, by Cara Murez



The U.S. Food and Drug Administration on Wednesday approved the

first pill form of fecal microbiota—similar to what's known as fecal transplant therapy—to treat the bacterial infection *Clostridioides difficile,* one of the most common and deadly infections found in health care settings.

The drug, Vowst, is approved to prevent recurrence of *C. difficile* in people who have already had standard antibacterial treatment for recurrent infection. It contains live gut bacteria from stool samples donated by healthy people.

"Today's approval provides patients and healthcare providers a new way to help prevent recurrent *C. difficile* infection," said Dr. Peter Marks, of the FDA's Center for Biologics Evaluation and Research, in a news release announcing the approval. "The availability of a fecal microbiota product that can be taken orally is a significant step forward in advancing patient care and accessibility for individuals who have experienced this disease that can be potentially life-threatening."

C. difficile is associated with between 15,000 and 30,000 deaths in the United States each year, the agency said.

The risk of infection is higher in people over 65 or those who have weakened immune systems, those who are hospitalized or in nursing homes and those who have a history of *C. difficile* infection.

Taking antibiotics for an infection can also alter the balance of the gut's microorganisms, allowing *C. difficile* to take hold, so Vowst could get around that issue.

C. difficile infection causes diarrhea, abdominal pain, fever and sometimes organ failure and death. Each time someone gets infected, the risk of reinfection grows.

But treatment with fetal microbiota can help restore a person's normal gut bacteria.

Before now, such treatments have been administered rectally. Last year, the FDA approved another pharmaceutical-grade product to fight *C. difficile*, but it is delivered rectally.

The FDA's approval of Vowst was based on a randomized clinical trial and an open-label clinical study.

In the randomized study in which 89 participants received Vowst and 93 received a placebo, the recurrence of infection was lower with the pill after eight weeks, at 12.4% for the medication group vs. 39.8% for the placebo group.

Another analysis of 90 patients who received Vowst, compared to 92 who received a placebo, found that side effects included bloating, fatigue, constipation, chills and diarrhea.

Eligible patients age 18 and up take four capsules of Vowst daily for three consecutive days.

Pill maker Seres Therapeutics Inc. has not revealed its pricing plan, the *AP* reported. The company said it is planning to market the treatment in collaboration with the food company Nestle.

"Recurrent *C. difficile* infection significantly impacts patients' quality of life, both physically and emotionally, leaving many living in tremendous fear of future recurrences. Patients have been waiting for new treatment options that address a key concern: prevention of an additional CDI [*C. difficile* infection] recurrence," Christian Christian John Lillis, executive director at Peggy Lillis Foundation for C. diff Education and Advocacy, said in a company news release announcing the approval.

Although donors and their stool are screened for pathogens before the stool is processed for the medication, there is a risk that someone can get an illness through the pill, the FDA noted. Vowst may also contain food allergens.

More information: The U.S. Centers for Disease Control and Prevention has more on *C. difficile*

Citation: FDA approves first pill for fecal transplant therapy (2023, April 27) retrieved 13 May 2023 from https://medicalxpress.com/news/2023-04-fda-pill-fecal-transplant-therapy.html