# First FDA-approved fecal-based treatment helps fight a tough superbug

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

first fecal microbiota treatment, aimed at helping adults battling tough-to-treat Clostridium difficile (C. diff) infections.

"Today's approval of Rebyota is an advance in caring for patients who have recurrent C. difficile infection [CDI]," said Dr. Peter Marks, director of the FDA's Center for Biologics Evaluation and Research.

"Recurrent CDI impacts an individual's quality of life and can also potentially be life-threatening," Marks said in an agency news release. "As the first FDA-approved fecal microbiota product, today's action represents an important milestone, as it provides an additional approved option to prevent recurrent CDI."

Prior to this approval, the infection has been treated using stool samples from healthy donors. Adding healthy bacteria from the donor gut in what is called fecal transplant helps fight the recipient's infection.

Rebyota, from Ferring Pharmaceuticals Inc., is still prepared from human stool. Donors are tested for a range of transmissible pathogens, though there is still the possibility of transmitting infections, the FDA noted. The treatment is administered rectally in one dose.

Two randomized, double-blind clinical studies and some open label clinical studies were completed prior to the approval to assess safety, involving a total of 978 adults.

In one study, the most common side effects among 180 Rebyota recipients when compared to 87 placebo recipients were abdominal pain, diarrhea, abdominal bloating, gas and nausea. Those patients had received one or more doses of Rebyota or a placebo 24 to 72 hours after completing antibiotic treatment and their CDI was under control, the FDA said.

The FDA evaluated the treatment's effectiveness through analyzing data from a randomized, double-blind, placebo-controlled, multi-center study.

This included 177 adults who received one dose of Rebyota and 85 who received one dose of placebo. The analysis also incorporated success rates from a different placebo-controlled study in which 39 adults received one dose of Rebyota and one dose of placebo, and another 43 adults received two doses of placebo.

Taking results from both studies, the overall success rate in preventing recurrent CDI for eight weeks was 70.6% in the Rebyota group and 57.5% in the placebo group.

CDI can cause diarrhea and significant inflammation of the colon. About 15,000 to 30,000 die from infection with the C. diff bacteria in the United States each year, the Associated Press reported.

It can happen after taking antibiotics in certain circumstances, particularly if that changes the microorganisms in the gut, allowing C. diff to multiply and release toxins. Being older than 65, hospitalization, having a weakened immune system and a previous history of CDI are risk factors.

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