

News From the Food and Drug Administration

New Option for Patients With Allergy to Chemotherapy Component

The FDA has [approved](#) an alternative for patients with acute lymphoblastic leukemia or lymphoblastic lymphoma who are allergic to *Escherichia coli*-derived asparaginase products in their chemotherapy regimen.

Marketed as Rylaze, asparaginase *Erwinia chrysanthemi* (recombinant)-rywn, is indicated for adults and children aged 1 month or older. According to the FDA, about 20% of patients are allergic to the [asparaginase enzyme](#) that's isolated from *E coli* bacteria. Asparaginase is an important chemotherapy component because it leads to protein synthesis inhibition and apoptosis in cancer cells. Another product made from a different bacterium for patients with allergies was approved in 2011, but it's been in short supply due to manufacturing issues at the only company that makes it. As a result, interruptions in therapy have led to [worse outcomes](#) for patients.

According to the FDA, approval was based on data from a [clinical trial](#) involving 102 patients. The main outcome measure was determining the proportion of patients whose blood level of the drug reached at least 0.1 IU/mL, which predicts clinical efficacy, at 48 hours. The trial results showed that 94% of patients achieved that level at the recommended dosage.

The most common adverse events were abnormal liver tests, nausea, musculoskeletal pain, fatigue, infection, headache, fever, allergic reaction, low white blood cell count, reduced appetite, sores or swelling in the mouth, bleeding, and hyperglycemia. One participant died of an infection, and 55% had a serious adverse reaction.

Cyclosporiasis Action Plan Aims to Reduce Food Contamination

In response to increasing foodborne illness outbreaks linked with the *Cyclospora*

cayetanensis bacterium, the FDA and the US Centers for Disease Control and Prevention (CDC) have developed an [action plan](#) focused on detection, prevention, and education.

Over the past 3 years, CDC [data](#) indicate that more than 6000 cyclosporiasis cases have been traced to US produce. Previously, most US cases were linked with travel to endemic areas or eating contaminated imported produce. However, the bacterium has increasingly been detected on US produce and in surface water at domestic farms. Outbreaks usually are seasonal, beginning in May and lasting until August. The foods involved include fresh US-grown basil, cilantro, mesclun lettuce, raspberries, and snow peas.



The plan includes a multipronged effort to educate farmers on the need for better sanitation practices—infection is transmitted in human feces. A fact [sheet](#) emphasizes the importance of training farm workers in proper hand hygiene and use of bathroom facilities made available for them. Educational [materials](#) on produce safety developed in conjunction with industry groups are available online.

In addition, the action plan outlines the need for more industry, academic, and regulatory collaboration to improve *C cayetanensis* testing, genotyping methods, and control measures on farms. FDA officials also

intend to work with the CDC to examine trends in US cyclosporiasis outbreaks.

First Oral Blood Thinner Is Approved for Children

The FDA [approved](#) dabigatran etexilate as the first oral blood thinner for children aged 3 months to 11 years who have venous thromboembolism and received injectable blood thinners for at least 5 days. Previously, the only anticoagulant approved for children was an injectable formulation.

"The FDA is committed to helping our youngest patients with serious medical conditions have treatments that are relatively easy to take," Ann Farrell, MD, director of the FDA's Division of Non-Malignant Hematology, said in a statement.

The agency also approved the oral pellets to prevent recurrent blood clots in the same age group after treatment for a first venous thromboembolism is completed. Oral capsules received approval for children aged 8 years or older after at least 5 days of injected blood thinners and to prevent recurrent clots after completion of treatment for a first venous thromboembolism.

The approval was based on results from an open-label [clinical trial](#) involving 267 children who were randomized to receive oral dabigatran etexilate or usual care. According to the FDA, about 46% of the group who took the oral drug met a composite end point—not dying from a blood clot, having completely resolved blood clots, or having no additional blood clots—compared with about 42% of the patients who received standard care.

The most common adverse events in children were digestive symptoms and bleeding. The drug also includes a boxed warning cautioning that early discontinuation can increase the risk of blood clots and that blood accumulated in the spine in patients undergoing spinal procedures can cause serious adverse events. — **Bridget M. Kuehn, MSJ**

Note: Source references are available through embedded hyperlinks in the article text online.