



Peter Baer  
Senior Regulatory Specialist  
Fresenius Kabi USA, LLC  
3 Corporate Drive  
Lake Zurich, IL 60047

September 5, 2024

Re: Docket No. FDA-2024-P-2513

Dear Mr. Baer:

This letter responds to your citizen petition received on March 5, 2024, requesting that the Food and Drug Administration (FDA) determine whether Flagyl, (metronidazole), Tablets, 250 milligrams (mg) and 500 mg has been withdrawn for reasons of safety or efficacy.

FDA has reviewed its records and determined that Flagyl, (metronidazole), Tablets, 250 mg and 500 mg, was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Flagyl, (metronidazole), Tablets, 250 mg and 500 mg, in the “Discontinued Drug Product List” section of Approved Drug Products With Therapeutic Equivalence Evaluations (the Orange Book).

Enclosed is a copy of the Federal Register notice that announces the FDA determination. If you require any further information, please feel free to email me at [Neerja.Razdan@fda.hhs.gov](mailto:Neerja.Razdan@fda.hhs.gov).

Sincerely,

**Neerja Razdan -**  
**S**

Digitally signed by Neerja  
Razdan -S  
Date: 2024.09.05 10:18:38 -04'00'

Neerja Razdan  
Office of Regulatory Policy  
Center for Drug Evaluation and Research

Enclosure