



Juan Camilo Arjona Ferreira
Head, Organon Research and Development and Chief Medical Officer
Organon USA, LLC
30 Hudson Street
Jersey City, NJ 07302

August 14, 2024

Re: Docket No. FDA-2024-P-1378

Dear Mr. Arjona Ferreira:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on March 5, 2024. Your petition requests that FDA apply certain standards to any abbreviated new drug application (ANDA) that references NEXPLANON (etonogestrel implant). You also request that FDA revise a product-specific draft guidance that is consistent with your petition.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Carol
Bennett -S

Digitally signed by Carol
Bennett -S
Date: 2024.08.14
12:16:56 -04'00'

Carol J. Bennett
Acting Director
Office of Regulatory Policy
Center for Drug Evaluation and Research