August 23, 2022

Timothy R. Cote
CEO, Only Orphans Cote LLC
88 Ames Street, Apt. 613
Cambridge, MA 02142

Sent via email to: haris@onlyorphanscote.com

Re: Citizen Petition, Docket # FDA-2022-P-0237

Dear Mr. Cote:

This letter is in response to your citizen petition filed with the Food and Drug Administration (FDA) on February 25, 2022. Your citizen petition refers to applications under review at FDA by the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), the Center for Devices and Radiological Health (CDRH), and the Office of Orphan Products Development (OOPD) and states that "[c]ontinuing the advancement of these applications through the FDA regulatory process would allow Russian companies access to the US market that they currently do not have." Your petition requests that "the Commissioner immediately and completely freeze all administrative actions on any regulatory requests from pharmaceutical and medical device companies headquartered in Russia or with majority Russian ownership."

FDA has reviewed your citizen petition and is denying your request in accordance with 21 C.F.R. § 10.30(e)(2)(ii). For regulatory matters that are subject to FDA oversight, federal statutes and regulations govern FDA's regulatory and oversight role. The review of applications by CDER, CBER, CDRH, and OOPD is governed by the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Public Health Service Act (PHS Act), and the regulations set forth at 21 C.F.R. Chapter 1, Subchapters D, F, and H. Under these legal authorities, FDA is not directed to consider the country where a pharmaceutical or medical device company is headquartered when we decide whether to take action on a regulatory request from that company. We are also not directed to consider the citizenship of a company's owners.

We have deep concern for the health and safety of the Ukrainian people during the ongoing Russian invasion of Ukraine and FDA stands with the people of Ukraine as they bravely defend their country.

FDA will continue to monitor the situation concerning the ongoing Russian invasion of Ukraine and the impact on FDA-regulated products and industries.

Sincerely,

Lauren Roth -S

Digitally signed by Lauren Roth -S
Date: 2022.08.23 16:30:10 -04'00'

Lauren K. Roth

Associate Commissioner for Policy

Cc: FDA's Dockets Management Staff