

Division of Dockets Management, Food and Drug Administration, Room 1061, 5630 Fishers Lane, Rockville, MD 20852.

Date: February 22, 2022

The undersigned submits this petition under Title 21, Chapter I, Subchapter A, Part 10, Subpart B Section 10.30, Citizen petition.

Action Requested:

This emergency petition requests 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.

Statement of Grounds:

On February 21, 2022 Russia invaded Ukraine, starting the largest military conflagration in Europe since the second world war. President Biden has promised a broad array of severe economic sanctions against Russia.

Russia's fledgling biotechnology sector is still quite small, and it is state-supported. For Russia, biotechnology and pharmaceuticals are very much an emerging industry, yet one with considerable future potential. By contrast, the US biotechnology sector is the largest and most lucrative in the world. Applicants from around the globe, including Russia, vie for entry into US markets, and FDA regulatory procedures are the gateway to our markets.

This petitioner is a regulatory consultant and former FDA Director and is well aware that there exist many Russian pharmaceutical/biotech countries with applications under review at FDA by the Center for Drugs Evaluation and Research, the Center for Biologics Evaluation and Research, the Center for Devices and Radiologic Health and the Office of Orphan Products Development. Identifying information about these applications is confidential and cannot be publicly released, nevertheless their existence is indisputable.

Continuing 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. This would be antithetical to the premise that Russia must pay economic consequences for invading its neighbors. Therefore, I petition for immediately and completely freeze all administrative action on any regulatory requests from pharmaceutical companies headquartered in Russia or with majority Russian ownership.

Environmental Impact: NA

Economic Impact: Negligable

Certification:

The undersigned certifies, that to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Signature

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Name of Petitioner

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Signed

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