DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

February 4, 2022

Jianqing Wu, Ph.D.,J.D.
(b) (6)
[redacted]

Sent via email to: (b) (6) [redacted]

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug suspend all outstanding mRNA vaccine use authorizations, re-evaluate vaccines' effectiveness and safety, and revoke their use authorizations as soon as possible, and make a plan to systematically overhaul its approval framework.

1. Investigate medical science information laundering by monopolistic medical publishers and how they have suppressed new discoveries that would have thrown out the reductionist research and treatment model, knowingly produce flawed and fraudulent knowledge for their revenue in the name of science, pursuant to the implied power under 21 U.S. § 355(b)-(c), 42 U.S. § 262(a)(2), 21 U.S. §564(g)(2), 21 U.S. § 379dd, and 21 C.F.R. §§ 1.21;

2. Evaluate a true life model and reject the reductionist research and treatment model, and evaluate safety and effectiveness of the mRNA vaccines, pursuant to 21 U.S. § 355(b)-(c), 42 U.S. § 262(a)(2), 21 U.S. § 564(g)(2), and 21 U.S. § 379dd;

3. Suspend all outstanding mRNA vaccine use authorizations and revoke same, pursuant to 21 U.S. § 564(g)(2). All dangers and potential risks are present in all mRNA vaccines and all flaws in the research model, data analysis, and conclusions have impacted the approval of all mRNA vaccines;

4. Urge FDA to initiate investigation with DOJ, FTC, FCC, etc. to understand the extent of criminal violations by information launders, particularly, antitrust violation, wire fraud violation, and wastes of massive federal research funds attributable to the conduct of monopolistic medical publishers. The authority is implied by FDA statutory mission to protect public health.

5. Request FDA to overhaul its approval framework: rejecting the drugs-for-health hypothesis, adopting a holistic analysis approach, avoiding trade art and junk science, restructuring advisory committee structure and member compositions, pursuant to implied

power provided in 21 U.S. § 379dd. Since this will take time, FDA does not need to address this request within 180 days, I will follow up by filing my continuous petitions.

6. The outcome of this petition will affect the health and lives of the U.S. population and potentially billions of people globally. However, federal government, state governments, foundations, etc. generally do not provide funding for researches for finding vaccines risks. Due to such funding biases and suppression of vital researches, Petitioner has to rely on observations, "misinformation", and "underground" data (per the characterization of information-launders) in this petition. FDA should bear responsibility to validate the accuracy of information from such sources. However, even if FDA rejects all "misinformation' and "underground" data, this petition still invalidates research conclusions that FDA has relied upon in granting mRNA vaccines use authorizations.

7. Petitioner started peerless researches as early as the start of the COVID-19 pandemic, but do not get any support from any peers, any funding agencies, and any media. Moreover, this petition is based on a different life model which is backed up by an extremely large amount of factual findings by independent researchers. In the eyes of people who have gotten used to the reductionist "science", the petition may appear to contain inaccuracies, inconsistent data, non-conventional expressions, etc. Those problems cannot be addressed until readers fully understand the new life model. If Petitioner spends years to address those problems, all damages to the U.S. population and humankind will be quickly realized. Petitioner therefore has a need to file this petition without any peer comment and review. The extraordinary circumstance justifies this decision. I hope that public readers of this petition will provide constructive feedback during the review period. Therefore, Petitioner requests FDA to grant a permission to file one to more updated petitions to clarify all difficulties that may inherently arise from evaluating two different science frameworks.

The petition was received and processed under CFR 10.30 by this office on 02/04/2022.

It was assigned docket number FDA-2022-P-0122. Please refer to this docket number in future correspondence on this subject with the Agency.

Also, note that the acceptance of the petition for filing is a procedural matter and in no way reflects the agency's decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-bigby -S

Digitally signed by Dynna Gorham-bigby -S
Date: 2022.02.07 13:57:28 -05'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
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