Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM 2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6143

MAJORITY (202) 225–5051 MINORITY (202) 225–5074 http://oversight.house.gov

March 30, 2020

Mr. Barry Migliorini Chief Executive Officer Wellness Matrix Group, Inc. 17011 Beach Blvd., 9th Floor Huntington Beach, CA 92647

Dear Mr. Migliorini:

The Subcommittee on Economic and Consumer Policy requests information about your company's coronavirus-related products, particularly the CoronaCide COVID-19 IgM / IgG Rapid Test, which your company claimed can be performed "in the home or at the bedside," and the CS-28 Disinfectant Protectorant and CS-28 Disinfectant Sanitizer, each of which you offered to sell for \$500 for one gallon and claimed "lasts for 28 days or more," "kills corona on contact," and "stops COVID-19 from latching onto surfaces and spreading."

On March 20, 2020, the Food and Drug Administration (FDA) cautioned against using at-home testing kits since their accuracy has not been determined.² On March 21, 2020, FDA made clear that its Emergency Use Authorization Guidelines bar the use of at-home sample collection and that it "has not authorized any test that is available for purchase for testing yourself at home for COVID-19."³

FDA's policy for coronavirus serology tests like the CoronaCide test states clearly that it "does not apply to at home testing." FDA's policy also requires that certain caveats be included with serology tests, including that "[t]his test has not been reviewed by the FDA," "[n]egative results do not rule out SARS-CoV-2 infection," and "[r]esults from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status."

¹ STOPCORONA28, *Home Page* (archived at http://archive.is/https://www.stopcorona28.com/).

² Food and Drug Administration, *Coronavirus (COVID-19) Update: FDA Alerts Consumers About Unauthorized Fraudulent COVID-19 Test Kits* (Mar. 20, 2020) (online at www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-alerts-consumers-about-unauthorized-fraudulent-covid-19-test-kits).

³ Food and Drug Administration, *FAQs on Diagnostic Testing for SARS-CoV-2* (Mar. 21, 2020) (online at www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2).

⁴ Food and Drug Administration, *Policy for Diagnostic Tests for Coronavirus Disease-2019 During the Public Health Emergency* (Mar. 16, 2020) (online at www.fda.gov/media/135659/download).

The Subcommittee requests responses to the following questions by March 31, 2020, regarding your company's coronavirus-related products:

- 1. When did your company start offering the following products for sale to consumers and, if you are no longer offering them for sale, when did you stop:
 - a. CoronaCide COVID-19 IgM / IgG Rapid Test or other at-home test kits?
 - b. CS-28 Disinfectant Protectorant or other protectorants or coatings?
 - c. CS-28 Disinfectant Sanitizer or other sanitizers?
- 2. How many of the following products has your company sold, how many did you ship, and how much did you charge for:
 - a. CoronaCide COVID-19 IgM / IgG Rapid Test or other at-home test kits?
 - b. CS-28 Disinfectant Protectorant or other protectorants or coatings?
 - c. CS-28 Disinfectant Sanitizer or other sanitizers?
- 3. Do you intend to refund to consumers amounts they paid for at-home coronavirus test kits, and if so, when and how you will you do so?
- 4. What information did you provide with your coronavirus tests regarding:
 - a. Status with FDA?
 - b. Significance of negative results?
 - c. Significance of positive results?
 - d. Whether the test could be used as the sole basis to diagnose or exclude coronavirus infection?
- 5. What support do you have for your claim that the CoronaCide test kit is "FDA Registered"?
- 6. For the CS-28 Disinfectant Protectorant and CS-28 Disinfectant Sanitizer products, what are the active ingredients, and what support do you have for claims that the product:
 - a. "lasts for 28 days or more"?
 - b. "kills corona on contact"?
 - c. "stops COVID-19 from latching onto surfaces and spreading"?
 - d. is "non-toxic"?
 - e. is "generally regarded as safe"?
 - f. "does not irritate skin"?
 - g. "does not bioaccumulate"?
- 7. What is your company's connection to the CoronaCide company based in Sandy, Utah?

Mr. Barry Migliorini Page 3

The Committee on Oversight and Reform is the principal oversight committee of the House of Representatives and has broad authority to investigate "any matter" at "any time" under House Rule X. If you have any questions regarding this request, please contact Subcommittee staff at (202) 225-5051.

Sincerely,

Raja Krishnamoorthi

Chairman

Subcommittee on Economic and Consumer Policy

Katie Porter

Member of Congress

Enclosure

cc: The Honorable Michael Cloud, Ranking Member

Responding to Committee Document Requests

- 1. In complying with this request, produce all responsive documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, and representatives acting on your behalf. Produce all documents that you have a legal right to obtain, that you have a right to copy, or to which you have access, as well as documents that you have placed in the temporary possession, custody, or control of any third party.
- 2. Requested documents, and all documents reasonably related to the requested documents, should not be destroyed, altered, removed, transferred, or otherwise made inaccessible to the Committees.
- 3. In the event that any entity, organization, or individual denoted in this request is or has been known by any name other than that herein denoted, the request shall be read also to include that alternative identification.
- 4. The Committees' preference is to receive documents in electronic form (i.e., CD, memory stick, thumb drive, or secure file transfer) in lieu of paper productions.
- 5. Documents produced in electronic format should be organized, identified, and indexed electronically.
- 6. Electronic document productions should be prepared according to the following standards:
 - a. The production should consist of single page Tagged Image File ("TIF"), files accompanied by a Concordance-format load file, an Opticon reference file, and a file defining the fields and character lengths of the load file.
 - b. Document numbers in the load file should match document Bates numbers and TIF file names.
 - c. If the production is completed through a series of multiple partial productions, field names and file order in all load files should match.
 - d. All electronic documents produced to the Committees should include the following fields of metadata specific to each document, and no modifications should be made to the original metadata:

BEGDOC, ENDDOC, TEXT, BEGATTACH, ENDATTACH, PAGECOUNT, CUSTODIAN, RECORDTYPE, DATE, TIME, SENTDATE, SENTTIME, BEGINDATE, BEGINTIME, ENDDATE, ENDTIME, AUTHOR, FROM, CC, TO, BCC, SUBJECT, TITLE, FILENAME, FILEEXT, FILESIZE, DATECREATED, TIMECREATED, DATELASTMOD, TIMELASTMOD,

INTMSGID, INTMSGHEADER, NATIVELINK, INTFILPATH, EXCEPTION, BEGATTACH.

- 7. Documents produced to the Committees should include an index describing the contents of the production. To the extent more than one CD, hard drive, memory stick, thumb drive, zip file, box, or folder is produced, each should contain an index describing its contents.
- 8. Documents produced in response to this request shall be produced together with copies of file labels, dividers, or identifying markers with which they were associated when the request was served.
- 9. When you produce documents, you should identify the paragraph(s) or request(s) in the Committees' letter to which the documents respond.
- 10. The fact that any other person or entity also possesses non-identical or identical copies of the same documents shall not be a basis to withhold any information.
- 11. The pendency of or potential for litigation shall not be a basis to withhold any information.
- 12. In accordance with 5 U.S.C.§ 552(d), the Freedom of Information Act (FOIA) and any statutory exemptions to FOIA shall not be a basis for withholding any information.
- 13. Pursuant to 5 U.S.C. § 552a(b)(9), the Privacy Act shall not be a basis for withholding information.
- 14. If compliance with the request cannot be made in full by the specified return date, compliance shall be made to the extent possible by that date. An explanation of why full compliance is not possible shall be provided along with any partial production.
- 15. In the event that a document is withheld on the basis of privilege, provide a privilege log containing the following information concerning any such document: (a) every privilege asserted; (b) the type of document; (c) the general subject matter; (d) the date, author, addressee, and any other recipient(s); (e) the relationship of the author and addressee to each other; and (f) the basis for the privilege(s) asserted.
- 16. If any document responsive to this request was, but no longer is, in your possession, custody, or control, identify the document (by date, author, subject, and recipients), and explain the circumstances under which the document ceased to be in your possession, custody, or control.
- 17. If a date or other descriptive detail set forth in this request referring to a document is inaccurate, but the actual date or other descriptive detail is known to you or is otherwise apparent from the context of the request, produce all documents that would be responsive as if the date or other descriptive detail were correct.

- 18. This request is continuing in nature and applies to any newly-discovered information. Any record, document, compilation of data, or information not produced because it has not been located or discovered by the return date shall be produced immediately upon subsequent location or discovery.
- 19. All documents shall be Bates-stamped sequentially and produced sequentially.
- 20. Two sets of each production shall be delivered, one set to the Majority Staff and one set to the Minority Staff. When documents are produced to the Committee on Oversight and Reform, production sets shall be delivered to the Majority Staff in Room 2157 of the Rayburn House Office Building and the Minority Staff in Room 2105 of the Rayburn House Office Building. When documents are produced to the Committee on Financial Services, production sets shall be delivered to the Majority Staff in Room 2129 of the Rayburn House Office Building and the Minority Staff in Room 4340 of the O'Neill House Office Building. When documents are produced to the Permanent Select Committee on Intelligence, production sets shall be delivered to Majority and Minority Staff in Room HVC-304 of the Capital Visitor Center.
- 21. Upon completion of the production, submit a written certification, signed by you or your counsel, stating that: (1) a diligent search has been completed of all documents in your possession, custody, or control that reasonably could contain responsive documents; and (2) all documents located during the search that are responsive have been produced to the Committee.

Definitions

The term "document" means any written, recorded, or graphic matter of any nature 1. whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to, the following: memoranda, reports, expense reports, books, manuals, instructions, financial reports, data, working papers, records, notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, communications, electronic mail (email), contracts, cables, notations of any type of conversation, telephone call, meeting or other inter-office or intra-office communication, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments of any of the foregoing, as well as any attachments or appendices thereto), and graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, microfiche, microfilm, videotape, recordings and motion pictures), and electronic, mechanical, and electric records or representations of any kind (including, without limitation, tapes, cassettes, disks, and recordings) and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, disk, videotape, or otherwise. A document bearing any notation not a

- part of the original text is to be considered a separate document. A draft or non-identical copy is a separate document within the meaning of this term.
- 2. The term "communication" means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether in a meeting, by telephone, facsimile, mail, releases, electronic message including email (desktop or mobile device), text message, instant message, MMS or SMS message, message application, or otherwise.
- 3. The terms "and" and "or" shall be construed broadly and either conjunctively or disjunctively to bring within the scope of this request any information that might otherwise be construed to be outside its scope. The singular includes plural number, and vice versa. The masculine includes the feminine and neutral genders.
- 4. The term "including" shall be construed broadly to mean "including, but not limited to."
- 5. The term "Company" means the named legal entity as well as any units, firms, partnerships, associations, corporations, limited liability companies, trusts, subsidiaries, affiliates, divisions, departments, branches, joint ventures, proprietorships, syndicates, or other legal, business or government entities over which the named legal entity exercises control or in which the named entity has any ownership whatsoever.
- 6. The term "identify," when used in a question about individuals, means to provide the following information: (a) the individual's complete name and title; (b) the individual's business or personal address and phone number; and (c) any and all known aliases.
- 7. The term "related to" or "referring or relating to," with respect to any given subject, means anything that constitutes, contains, embodies, reflects, identifies, states, refers to, deals with, or is pertinent to that subject in any manner whatsoever.
- 8. The term "employee" means any past or present agent, borrowed employee, casual employee, consultant, contractor, de facto employee, detailee, fellow, independent contractor, intern, joint adventurer, loaned employee, officer, part-time employee, permanent employee, provisional employee, special government employee, subcontractor, or any other type of service provider.
- 9. The term "individual" means all natural persons and all persons or entities acting on their behalf.