CAROLYN B. MALONEY, NEW YORK
CHAIRWOMAN

ONE HUNDRED SEVENTEENTH CONGRESS

JAMES COMER, KENTUCKY
RANKING MINORITY MEMBER

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
https://oversight.house.gov

November 8, 2021

Mr. Vincent Schuman
Chief Executive Officer
Next Generation Labs LLC
8505 Commerce Avenue
San Diego, CA 92121

Dear Mr. Schuman:

I write to request documents and information concerning the manufacture and sale of synthetic nicotine by Next Generation Labs. I am deeply concerned about the rise of synthetic nicotine—a nascent industry that is largely unregulated by the Food and Drug Administration (FDA).[1] Next Generation Labs manufactures nicotine at an industrial scale and supplies it to manufacturers of e-cigarettes and e-liquids for use in their products.[2] Next Generation Labs claims to be "the market leader" in synthetic nicotine and the "dominant and first player in the market."[3] Your company supplies to both e-cigarette manufacturers and vape shops and claims to be in over 60 vape brands and other nicotine products in the U.S. and abroad.[4]

Next Generation Labs has projected a "staggering 1,800%" growth this year over 2020 sales volume.[5] That predicted growth appears to be linked to the U.S. market, with a company co-founder stating that "the coming months are going to see the introduction of multiple so-called synthetic nicotine products that are specifically targeted at the U.S."[6]

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[1] *What You Need to Know About New Synthetic Nicotine Products*, Truth Initiative (April 6, 2021) (online at https://truthinitiative.org/research-resources/harmful-effects-tobacco/what-you-need-know-about-new-synthetic-nicotine-products).

[2] Next Generation Labs, *Home Page* (online at www.nextgenerationlabs.com/) (accessed Oct. 7, 2021).

[3] *A Real Up and Comer: Synthetic Nicotine*, Tobacco Asia (Feb. 14, 2021) (online at www.tobaccoasia.com/features/a-real-up-and-comer-synthetic-nicotine/).

[4] Next Generation Labs, *The Synthetic Nicotine Marketplace: Next Generation Delivery USA 2021* (online at www.nextgenerationlabs.com/wp-content/uploads/2021/06/THE-SYNTHETIC-NICOTINE-MARKETPLACE-NGL.pdf) (accessed Oct. 6, 2021); Next Generation Labs, *Press Release: Next Generation Labs Warns of Surge in Fake and Counterfeit Synthetic Nicotine Products Coming from China* (Sept. 17, 2021) (online at www.prweb.com/releases/next_generation_labs_warns_of_surge_in_fake_and_counterfeit_synthetic_nicotine_vape_products_coming_from_china/prweb17398859.htm).

[5] *A Real Up and Comer: Synthetic Nicotine*, Tobacco Asia (Feb. 14, 2021) (online at www.tobaccoasia.com/features/a-real-up-and-comer-synthetic-nicotine/).

[6] *Id.*

Projected growth in the United States comes at a time when FDA has recently removed from the market millions of flavored e-cigarette and e-liquid products.[7] In response, some e-cigarette and e-liquid manufacturers, banned from legally selling their products, reportedly plan to switch to synthetic nicotine in an effort to avoid FDA regulation.[8] Next Generation Labs appears to support this approach, with its co-founder, Ron Tully, offering the following thoughts on the FDA laws and regulations governing nicotine: "If the statute has been ill-conceived, and the regulation has been ill-drafted, it is not the responsibility of the industry to conform to some kind of idea that you can't innovate in those spaces where the legislation doesn't occur."[9]

Next Generation Labs has also claimed that scammers are selling fake synthetic nicotine. In particular, it recently warned that Chinese manufacturers may be responsible for e-cigarettes in the United States being falsely advertised as containing synthetic nicotine, when they actually contain tobacco-derived nicotine.[10] Some of the false claims involve "manufacturers of nicotine claim[ing] to be selling 'synthetic nicotine' that is actually highly purified [tobacco-derived nicotine] (essentially devoid of tobacco residuals)."[11] We share your concern about these bad actors, and welcome all available information about them, as the acts that you have described could violate FDA law and could also constitute unfair and deceptive acts and practices under state and federal laws.

To assist the Subcommittee in its review of this matter, by November 22, 2021, please produce the following documents from January 1, 2016, to the present, unless otherwise indicated:

1. Documents sufficient to show all companies to which you supply synthetic nicotine capable of being used in e-cigarettes and/or e-liquids, including the address of the company, the dates and volumes of each order, and the cost of each order;

2. Documents sufficient to show that your synthetic nicotine products are not tobacco-derived;

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[7] Food and Drug Administration, *Tobacco Product Marketing Orders* (online at www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-products-marketing-orders) (accessed Oct. 5, 2021).

[8] *Some Vaping Companies Are Turning to Synthetic Nicotine to Outsmart the FDA*, Time (Sept. 17, 2021) (online at https://time.com/6098897/vaping-companies-synthetic-nicotine/).

[9] *The Rise of Synthetic Nicotine Risks Regulatory "Whack-a-Mole"*, Filter (Aug. 4, 2021) (online at https://filtermag.org/synthetic-nicotine-tobacco-free-pouches/).

[10] Next Generation Labs, *Press Release: Next Generation Labs Warns of Surge in Fake and Counterfeit Synthetic Nicotine Products Coming from China* (Sept. 17, 2021) (online at www.prweb.com/releases/next_generation_labs_warns_of_surge_in_fake_and_counterfeit_synthetic_nicotine_vape_products_coming_from_china/prweb17398859.htm).

[11] Next Generation Labs, *The Synthetic Nicotine Marketplace: Next Generation Delivery USA 2021* (online at www.nextgenerationlabs.com/wp-content/uploads/2021/06/THE-SYNTHETIC-NICOTINE-MARKETPLACE-NGL.pdf) (accessed Oct. 6, 2021).

3. All communications with customers and potential customers, from January 1, 2020, to the present, regarding:

    a. new synthetic nicotine customers and prospective new synthetic nicotine customers;

    b. increased orders from existing customers;

    c. synthetic nicotine and FDA;

    d. the legal and/or regulatory status of synthetic nicotine;

    e. addictiveness and/or abusability of synthetic nicotine; and

    f. counterfeit synthetic nicotine or tobacco-derived nicotine being marketed as synthetic nicotine;

4. All documents used in connection with communications with actual or prospective new customers, including sales prompts, information sheets, and brochures;

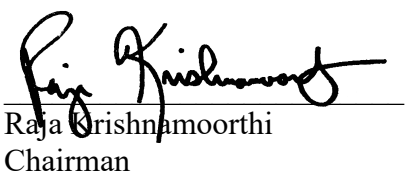
5. Documents sufficient to show all e-cigarette and e-liquid products that contain Next Generation Labs' synthetic nicotine;

6. Documents sufficient to show Next Generation Labs knowledge of all competitors that purport to manufacture and/or supply synthetic nicotine; and

7. All documents and information relating to Next Generation Labs' claims that companies have, or may have, falsely claimed that their products contain "synthetic nicotine."

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. An attachment to this letter provides additional instructions for responding to the Committee's request. 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

Enclosure

cc: The Honorable Michael Cloud, Ranking Member
Subcommittee on Economic and Consumer Policy

Responding to Oversight 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 Committee.

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 Committee's 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 Committee 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 Committee 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 Committee's 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, 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.

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

1. The term "document" means any written, recorded, or graphic matter of any nature 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.