BEFORE THE FEDERAL TRADE COMMISSION

In the Matter of CELLMARK BIOPHARMA LLC.

PETITION TO LIMIT OR QUASH CIVIL INVESTIGATIVE DEMAND BY CELLMARK BIOPHARMA LLC

Petitioner, CellMark Biopharma LLC ("CellMark"), hereby petitions the Federal Trade Commission ("FTC" or "Commission"), pursuant to 16 C.F.R. § 2.7(d), to limit or quash the Civil Investigative Demand ("CID") that it served on May 26, 2016. The FTC issued the CID pursuant to its alleged authority under § 20 of the Federal Trade Commission Act, 15 U.S.C. § 57b-1. An officer and the sole shareholder, Derek Vest ("Vest"), has received a target letter from the U.S. Attorney for the Middle District of Florida. In order to ensure that his Fifth Amendment right against self-incrimination is not waived by the production of information to the FTC, CellMark files this Petition to limit the production of any privileged information pursuant to the CID.

BACKGROUND

CellMark is a Delaware limited liability company formed in 2015. Vest is the company's sole shareholder. In 2016, CellMark began selling two products, CellAssure™ and Cognify™ made by contract manufacturers. CellAssure is a supplemental protein nutrition drink. Cognify is a mental cognition supplement. On May 26, 2016, the Commission served a Civil Investigative Demand ("CID") with 43 interrogatories (not counting subparts) and 34 document specifications. Ex. 1. The CID seeks information on broad topics, including corporate information, product

development and formulation, manufacturing, labels and advertising, claim substantiation, sales, and return/refund policies. The CID defines "Company" to mean:

> CellMark Biopharma LLC, its wholly or partially owned subsidiaries, unincorporated divisions, joint ventures, operations under assumed names or affiliates, and all directors, officers, members, employees, agents, consultants, and other persons working for or on behalf of the foregoing, including Derek Vest, Craig Pisaris-Henderson, Dr. Stan Headley, Anthony Spotora, and Erika Boliek.

Ex. 1 § I.H. The scope of search provision is similarly broad:

> This CID covers documents and information in your possession or under your actual or constructive custody or control including, but not limited to, documents and information in the possession, custody, or control of your attorneys, accountants, directors, officers, employees, and other agents and consultants, whether or not such documents and information were received from or disseminated to any person or entity.

Id. § II.I. The return date on the CID is June 14, 2016.

The Commission staff and CellMark had a meet and confer teleconference on June 6, 2016. During that conference, the parties discussed a schedule for producing information to the Commission, and the scope of the definitions and requests. CellMark informed the staff that Vest had received a criminal target letter from the U.S. Attorney for the Middle District of Florida. Ex. 2. The letter to Vest states that "you are now a target of a Federal Grand Jury investigation in this District into introducing and delivering for introduction into interstate commerce misbranded drugs and other matters and possible violations of federal criminal laws. The United States is prepared to proceed before a Federal Grand Jury to seek charges against you." On June 8, CellMark provided staff with a copy of that letter.

ARGUMENT

The act of compelling the production of interrogatory responses and documents implicates Vest's Fifth Amendment rights and the CID should be limited. The CID, while served on CellMark, requires Vest to produce information to the FTC. *See* Ex. 1 § I.H ("'Company' shall

mean CellMark ... and all directors, officers, members, employees, agents, consultants, and other persons working for or on behalf of the foregoing, including Derek Vest"). The CID further requires a search for documents and information in the possession of CellMark and its "attorneys, accountants, directors, officers, employees, and other agents and consultants, whether or not such documents and information were received from or disseminated to any person or entity." *Id.* § II.I.

Vest's turning over of the extensive information and documents specified in the CID would admit their existence and authenticity. Accordingly, CellMark seeks to limit the CID to ensure that its officer and sole shareholder, Vest, can protect and assert his Fifth Amendment privilege.

The Fifth Amendment protects a person from being compelled to produce information that would incriminate that person. *See, e.g., Fisher v. United States*, 425 U.S. 391, 397 (1976). The U.S. Supreme Court has long held that a government subpoena cannot compel the holder of documents and information to perform an act that may have testimonial aspects and an incriminating effect. See, e.g., *United States v. Doe*, 465 U.S. 605, 612 (1984). The act of production is privileged under the Fifth Amendment and cannot be compelled without a statutory grant of use immunity pursuant to 18 U. S. C. §§ 6002 and 6003. *Id.* at 617.

In *United States v. Hubbell*, 530 U.S. 27 (2000), the Court found that the act of producing documents in response to a subpoena may have a compelled testimonial aspect. The act of production itself may implicitly communicate statements of fact. By producing documents in compliance with a subpoena, the witness would admit that the papers existed, were in his possession or control, and were authentic. *Id.* at 36.

Hubbell also found that the Fifth Amendment protects a person who would be compelled to identify information and them produce it:

> It is apparent from the text of the subpoena itself that the prosecutor needed respondent's assistance both to identify potential sources of information and to produce those sources. See Appendix, infra. Given the breadth of the description of the 11 categories of documents called for by the subpoena, the collection and production of the materials demanded was tantamount to answering a series of interrogatories asking a witness to disclose the existence and location of particular documents fitting certain broad descriptions. The assembly of literally hundreds of pages of material in response to a request for "any and all documents reflecting, referring, or relating to any direct or indirect sources of money or other things of value received by or provided to" an individual or members of his family during a 3-year period, ... is the functional equivalent of the preparation of an answer to either a detailed written interrogatory or a series of oral questions at a discovery deposition. Entirely apart from the contents of the 13,120 pages of materials that respondent produced in this case, it is undeniable that providing a catalog of existing documents fitting within any of the 11 broadly worded subpoena categories could provide a prosecutor with a "lead to incriminating evidence," or "a link in the chain of evidence needed to prosecute."

Id. at 41-42. The Court concluded that:

> In sum, we have no doubt that the constitutional privilege against self-incrimination protects the target of a grand jury investigation from being compelled to answer questions designed to elicit information about the existence of sources of potentially incriminating evidence. That constitutional privilege has the same application to the testimonial aspect of a response to a subpoena seeking discovery of those sources. Before the District Court, the Government arguably conceded that respondent's act of production in this case had a testimonial aspect that entitled him to respond to the subpoena by asserting his privilege against self-incrimination.

Id. at 43-44.

On its face, the CID seeks the production of information and documents in Vest's possession by defining "Company" to include CellMark and "its directors, officers, members, employees, agents, consultants, and other persons working for or on behalf of the foregoing, including Derek Vest...." Ex. 1 § I.H; *see also id.* § II.I (requiring the search for and production of material by CellMark and its "attorneys, accountants, directors, officers, employees, and other

agents and consultants, whether or not such documents and information were received from or disseminated to any person or entity."). Compelling Vest to produce such information implicates his Fifth Amendment right against self-incrimination. CellMark understands that Vest does not intend to waive his constitutional rights. As such, the CID should be limited or quashed to the extent its requires the production of such protected material.

In addition, the Fifth Amendment is implicated when a witness is "compelled to take the witness stand and answer questions designed to determine whether he has produced everything demanded by the subpoena." *Hubbell*, 530 U.S. at 37. Here, the CID's instructions require a sworn certificate that "all of the documents, information and tangible things required" by the CID have been produced. Ex. 1 at 1-2. Thus, the CID should be limited to exclude the requirement that CellMark certify that all documents and information of Vest have been provided to the FTC.

Finally, CellMark, as a limited liability company and on behalf of its directors, officers, members, employees, agents, consultants and representatives, object to the CID based on the Fifth Amendment privilege against self-incrimination. Cases holding that the Fifth Amendment does not apply to corporate entities are no longer good law in light of *Citizens United v. FEC*, 558 U.S. 310 (2010) and *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014). In *Citizens United*, the Supreme Court ruled that the government cannot prohibit political expenditures by corporations based on the speaker's corporate identity. The *Hobby Lobby* decision recognized that a closely-held corporation had religious liberties.

Citizens United rejected the premise that a corporate entity's status, advantages of using the corporate form, or the potentially corrupting influence of corporations could justify denial of First Amendment rights. *Citizens United* requires a reexamination of the outdated rationales used to deny a corporation's right against self-incrimination. First, because *Citizens United* treats corporate entities as

persons capable of exercising their constitutional rights, the government can hardly still claim that the Fifth Amendment is a "purely personal" privilege belonging only to natural persons – especially because criminal statutes, as well as all the other prongs of the Fifth Amendment, treat a corporation as a "person." Second, because *Citizens United* explicitly rejects discrimination against corporations based upon the "special advantages" of the corporate form, that rationale can no longer serve as a basis to deny corporations a right against self-incrimination. Finally, the government's asserted interest in enforcing criminal laws against corporations can no longer stand as a reason for differential treatment, because there is no for applying that interest solely to corporate crime and not to crimes committed by individuals.

Corporations can invoke rights under other prongs of the Fifth Amendment. *See, e.g.*, *United States v. Martin Linen Supply Co.*, 430 U.S. 564, 569 (1977) (applying Fifth Amendment double jeopardy clause to corporation); *Mackin v. United States*, 117 U.S. 348 (1886) (applying grand jury clause to corporation); *Pennsylvania Coal Co. v. Mahon*, 260 U.S. 393, 412 (1922) (applying Fifth Amendment takings clause to corporation); *Noble v. Union River Logging R.R. Co.*, 147 U.S. 165, 171, 177 (1893) (applying Fifth Amendment due process clause to corporation). For four of the five prongs of the single-sentence Amendment, its subject – the word "person" – includes corporations. Only as to self-incrimination has the same word been given a different meaning.

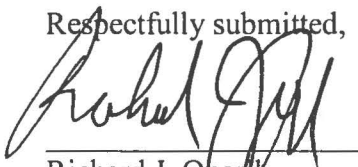
Thus, the Commission should quash or limit the CID to allow "the Company" (as broadly defined in the CID) to withhold information and documents pursuant to the Fifth Amendment's right against self-incrimination.

CONCLUSION

For the foregoing reasons, to the extent that the CID compels the production of interrogatory responses and documents protected by the Fifth Amendment, CellMark's Petition to Limit or Quash the CID should be granted.

Dated: June 13, 2016

Respectfully submitted,



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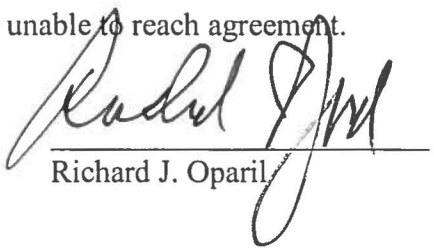
Counsel for Petitioner
CellMark BioPharma LLC

CERTIFICATION

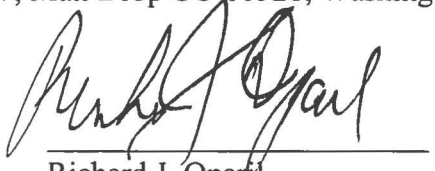
Pursuant to 16 C.F.R. § 2.7(d)(2), counsel for CellMark hereby certifies that counsel met and conferred with FTC counsel in a good faith attempt to resolve by agreement the issues set forth in this Petition, but the parties were unable to reach agreement.



Richard J. Oparil

CERTIFICATE OF SERVICE

I hereby certify that on June 13, 2016, I caused the original and 12 copies to the foregoing Petition to Limit or Quash with attached exhibits to be filed by hand delivery to the Secretary of the Federal Trade Commission, 601 New Jersey Ave., NW, Washington, DC 20580, and one copy to be served by email and hand delivery to Carolyn L. Hann, Esq., Federal Trade Commission, 600 Pennsylvania Ave., NW, Mail Drop CC-10528, Washington, DC 20580.



Richard J. Oparil

EXHIBIT 1

United States of America
Federal Trade Commission

CIVIL INVESTIGATIVE DEMAND

1. TO

CellMark Biopharma LLC
1591 Hayley Lane
Suite 201
Fort Myers, FL 33907

This demand is issued pursuant to Section 20 of the Federal Trade Commission Act, 15 U.S.C. § 57b-1, in the course of an investigation to determine whether there is, has been, or may be a violation of any laws administered by the Federal Trade Commission by conduct, activities or proposed action as described in Item 3.

2. ACTION REQUIRED

☐ You are required to appear and testify.

LOCATION OF HEARING	YOUR APPEARANCE WILL BE BEFORE
	DATE AND TIME OF HEARING OR DEPOSITION

☒ You are required to produce all documents described in the attached schedule that are in your possession, custody, or control, and to make them available at your address indicated above for inspection and copying or reproduction at the date and time specified below.

☒ You are required to answer the interrogatories or provide the written report described on the attached schedule. Answer each interrogatory or report separately and fully in writing. Submit your answers or report to the Records Custodian named in Item 4 on or before the date specified below.

☒ You are required to produce the tangible things described on the attached schedule. Produce such things to the Records Custodian named in Item 4 on or before the date specified below.

DATE AND TIME THE DOCUMENTS, ANSWERS TO INTERROGATORIES, REPORTS, AND/OR TANGIBLE THINGS MUST BE AVAILABLE

JUN 14 2016

3. SUBJECT OF INVESTIGATION

See attached resolution

4. RECORDS CUSTODIAN/DEPUTY RECORDS CUSTODIAN	5. COMMISSION COUNSEL
Connor Sands/Lynne Colbert Federal Trade Commission 600 Pennsylvania Ave , NW Mail Drop CC-10528 Washington, DC 20580	Carolyn L. Hann Federal Trade Commission 600 Pennsylvania Ave., NW Mail Drop CC-10528 Washington, DC 20580 202-326-2745

DATE ISSUED	COMMISSIONER'S SIGNATURE
May 24, 2016	Terrell McSweeny

INSTRUCTIONS AND NOTICES

The delivery of this demand to you by any method prescribed by the Commission's Rules of Practice is legal service and may subject you to a penalty imposed by law for failure to comply. The production of documents or the submission of answers and report in response to this demand must be made under a sworn certificate, in the form printed on the second page of this demand, by the person to whom this demand is directed or, if not a natural person, by a person or persons having knowledge of the facts and circumstances of such production or responsible for answering each interrogatory or report question. This demand does not require approval by OMB under the Paperwork Reduction Act of 1980.

PETITION TO LIMIT OR QUASH

The Commission's Rules of Practice require that any petition to limit or quash this demand be filed within 20 days after service, or, if the return date is less than 20 days after service, prior to the return date. The original and twelve copies of the petition must be filed with the Secretary of the Federal Trade Commission, and one copy should be sent to the Commission Counsel named in Item 5.

YOUR RIGHTS TO REGULATORY ENFORCEMENT FAIRNESS

The FTC has a longstanding commitment to a fair regulatory enforcement environment. If you are a small business (under Small Business Administration standards), you have a right to contact the Small Business Administration's National Ombudsman at 1-888-REGFAIR (1-888-734-3247) or www.sba.gov/ombudsman regarding the fairness of the compliance and enforcement activities of the agency. You should understand, however, that the National Ombudsman cannot change, stop, or delay a federal agency enforcement action.

The FTC strictly forbids retaliatory acts by its employees, and you will not be penalized for expressing a concern about these activities.

TRAVEL EXPENSES

Use the enclosed travel voucher to claim compensation to which you are entitled as a witness for the Commission. The completed travel voucher and this demand should be presented to Commission Counsel for payment. If you are permanently or temporarily living somewhere other than the address on this demand and it would require excessive travel for you to appear, you must get prior approval from Commission Counsel.

A copy of the Commission's Rules of Practice is available online at http://bit.ly/FTCRulesofPractice. Paper copies are available upon request.

Form of Certificate of Compliance*

I/We do certify that all of the documents, information and tangible things required by the attached Civil Investigative Demand which are in the possession, custody, control, or knowledge of the person to whom the demand is directed have been submitted to a custodian named herein.

If a document or tangible thing responsive to this Civil Investigative Demand has not been submitted, the objections to its submission and the reasons for the objection have been stated.

If an interrogatory or a portion of the request has not been fully answered or a portion of the report has not been completed, the objections to its submission and the reasons for the objections have been stated.

Signature _____

Title _____

Sworn to before me this day

_____ _____

_____
Notary Public

_____

*In the event that more than one person is responsible for complying with this demand, the certificate shall identify the documents for which each certifying individual was responsible. In place of a sworn statement, the above certificate of compliance may be supported by an unsworn declaration as provided for by 28 U.S.C. § 1746.

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

COMMISSIONERS: **Jon Leibowitz, Chairman**
Pamela Jones Harbour
William E. Kovacic
J. Thomas Rosch

RESOLUTION DIRECTING USE OF COMPULSORY PROCESS IN A NONPUBLIC INVESTIGATION OF UNNAMED PERSONS ENGAGED DIRECTLY OR INDIRECTLY IN THE ADVERTISING OR MARKETING OF DIETARY SUPPLEMENTS, FOODS, DRUGS, DEVICES, OR ANY OTHER PRODUCT OR SERVICE INTENDED TO PROVIDE A HEALTH BENEFIT OR TO AFFECT THE STRUCTURE OR FUNCTION OF THE BODY

File No. 0023191

Nature and Scope of Investigation:

To investigate whether unnamed persons, partnerships, or corporations, or others engaged directly or indirectly in the advertising or marketing of dietary supplements, foods, drugs, devices, or any other product or service intended to provide a health benefit or to affect the structure or function of the body have misrepresented or are misrepresenting the safety or efficacy of such products or services, and therefore have engaged or are engaging in unfair or deceptive acts or practices or in the making of false advertisements, in or affecting commerce, in violation of Sections 5 and 12 of the Federal Trade Commission Act, 15 U.S.C. §§ 45 and 52. The investigation is also to determine whether Commission action to obtain redress for injury to consumers or others would be in the public interest.

The Federal Trade Commission hereby resolves and directs that any and all compulsory processes available to it be used in connection with this investigation for a period not to exceed ten (10) years from the date of issuance of this resolution. The expiration of this ten (10) year period shall not limit or terminate the investigation or the legal effect of any compulsory process issued during the ten (10) year period. The Federal Trade Commission specifically authorizes the filing or continuation of actions to enforce any such compulsory process after expiration of the ten year period.

Authority to conduct investigation:

Sections 6, 9, 10, and 20 of the Federal Trade Commission Act, 15 U.S.C. §§ 46, 49, 50, and 57b-1, as amended; FTC Procedures and Rules of Practice, 16 C.F.R. § 1.1 et seq. and supplements thereto.

By direction of the Commission. Donald S. Clark

Donald S. Clark
Secretary

Issued: August 13, 2009

CIVIL INVESTIGATIVE DEMAND
SCHEDULE FOR PRODUCTION OF DOCUMENTS AND ANSWERS
TO WRITTEN INTERROGATORIES

I. DEFINITIONS

As used in this Civil Investigative Demand, the following definitions shall apply:

A. "**Advertisement**" or "**advertising**" or "**ad**" means any written or verbal statement, illustration, or depiction that promotes the sale of a good or service or is designed to increase consumer interest in a brand, good, or service. Advertising media include, but are not limited to, packaging and labeling; promotional materials; print; television; radio; and internet, social media, and other digital content.

B. "**And**," as well as "**or**," shall be construed both conjunctively and disjunctively, as necessary, in order to bring within the scope of any specification in this Schedule all information that otherwise might be construed to be outside the scope of the specification.

C. "**Any**" shall be construed to include "**all**," and "**all**" shall be construed to include the word "**any**."

D. "**CellMark Product(s)**" mean any of the following marketed or offered for sale by the Company:

1. Any cognitive function product, including Cognify; and

2. Any nutritional product, including CellAssure.

E. **"Chargeback"** shall mean a transaction that is returned as a financial liability to an acquirer by a card issuer, usually because of a disputed transaction. The acquirer may then return or "charge back" the transaction to the merchant.

F. "**CID**" means the Civil Investigative Demand, including the attached Resolution and this Schedule, and including the Definitions, Instructions, and Specifications.

G. **"Communication"** means any transmission or receipt of facts, information, opinions, or thought, whether conveyed in writing, orally, electronically, or by any other means, including written memorializations of oral communications.

H. **"Company**," shall mean CellMark Biopharma LLC, its wholly or partially owned subsidiaries, unincorporated divisions, joint ventures, operations under assumed names or affiliates, and all directors, officers, members, employees, agents, consultants, and other persons working for or on behalf of the foregoing, including Derek Vest, Craig Pisaris-Henderson, Dr. Stan Headley, Anthony Spotora, and Erika Boliek.

I. "**Component**" means any substance intended for use in the manufacture of a dietary

supplement, including those that may not appear in the finished batch of the dietary supplement. Component includes dietary ingredients and other ingredients.

J. "**Continuity Program**" means any plan, arrangement, or system under which a consumer receives periodic shipments of products or the provision of services without prior notification by the seller before each shipment or service period, regardless of any trial or approval period allowing the consumer to return or be reimbursed for the product or service.

K. "**Dietary ingredient**" means a vitamin, mineral, herb or other botanical, amino acid, dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any of above ingredients.

L. "**Document**" means the complete original and any non-identical copy (whether different from the original because of notations on the copy or otherwise), regardless of origin or location, of any written, typed, printed, transcribed, filmed, punched, or graphic matter of every type and description, however and by whomever prepared, produced, disseminated or made, including but not limited to any advertisement, book, pamphlet, periodical, contract, correspondence, file, invoice, memorandum, note, telegram, report, record, handwritten note, working paper, routing slip, chart, graph, paper, index, map, tabulation, manual, guide, outline, script, abstract, history, calendar, diary, agenda, minute, code book or label. **"Document" shall also include all documents, materials, and information, including Electronically Stored Information, within the meaning of the Federal Rules of Civil Procedure.**

M. "**Each**" shall be construed to include "**every**," and "**every**" shall be construed to include "**each**."

N. "**Electronically Stored Information**" or "**ESI**" means the complete original and any non-identical copy (whether different from the original because of notations, different metadata, or otherwise), regardless of origin or location, of any writings, drawings, graphs, charts, photographs, sound recordings, images, and other data or data compilations stored in any electronic medium from which information can be obtained either directly or, if necessary, after translation by you into a reasonably usable form. This includes, but is not limited to, electronic mail, instant messaging, videoconferencing, and other electronic correspondence (whether active, archived, or in a deleted items folder), word processing files, spreadsheets, databases, and video and sound recordings, whether stored on: cards; magnetic or electronic tapes; disks; computer hard drives, network shares or servers, or other drives; cloud-based platforms; cell phones, PDAs, computer tablets, or other mobile devices; or other storage media.

O. "**FTC**" or "**Commission**" means the Federal Trade Commission.

P. "**Identify**" or "**the identity of**" shall be construed to require identification of (a) natural persons by name, title, present business affiliation, present business address and telephone number, or if a present business affiliation or present business address is not known, the last known business and home addresses; and (b) businesses or other organizations by name, address, identities of natural persons who are officers, directors or managers of the business or organization, and contact persons, where applicable.

Q. **"Ingredient"** means any substance that is used in the manufacture of a dietary supplement and that is intended to be present in the finished dietary supplement. An ingredient includes, but is not necessarily limited to, a dietary ingredient.

R. **"Negative Option"** means, in an offer or agreement to sell or provide any goods or services, a provision under which the customer's silence or failure to take an affirmative action to reject goods or services or to cancel the agreement is interpreted by the seller as acceptance of the offer. The term includes a provision in offers or agreements involving automatic renewals, Continuity Programs, and Prenotification Negative Option Plans covered by the Commission's Rule entitled the "Use of Prenotification Negative Option Plans," 16 C.F.R. Part 425 (2014) (Prenotification Negative Option Rule).

S. **"Person"** or **"persons"** means all natural persons, corporations, partnerships, or other business associations and all other legal entities, including all members, officers, predecessors, assigns, divisions, affiliates, and subsidiaries.

T. **"Product Specification"** means the criteria that a product must meet for identity, strength, and composition, as established pursuant to 21 C.F.R. § 111.70(e).

U. **"Promotional material"** means any document or thing designed or used to create interest in the purchasing of goods or services that is not normally counted as advertising, including, but not limited to: press releases, video news releases, and other communications with any print, television, or radio media, or any website designer, developer, manager, or host, or any online service; coupons; product information provided to bloggers; and payments for shelf space.

V. **"Referring to"** or **"relating to"** means discussing, describing, reflecting, containing, analyzing, studying, reporting, commenting on, evidencing, constituting, setting forth, considering, recommending, concerning, or pertaining to, in whole or in part.

W. The singular shall include the plural, and the plural shall include the singular.

II. INSTRUCTIONS

A. **Sharing of Information:** The Commission often makes its files available to other civil and criminal federal, state, local, or foreign law enforcement agencies. The Commission may make information supplied by you available to such agencies where appropriate pursuant to the Federal Trade Commission Act and 16 C.F.R. § 4.11 (c) and (j). Information you provide may be used in any federal, state, or foreign civil or criminal proceeding by the Commission or other agencies.

B. **Meet and Confer:** You must contact **Carolyn Hann** at **(202) 326-2745** as soon as possible to schedule a meeting (telephonic or in person) to be held within fourteen (14) days after receipt of this CID, or before the deadline for filing a petition to quash, whichever is first, in order to discuss compliance and to address and attempt to resolve all issues, including issues relating to protected status and the form and manner in which claims of protected status will be

asserted, and the submission of ESI and other electronic productions as described in these Instructions. Pursuant to 16 C.F.R. § 2.7(k), you must make available personnel with the knowledge necessary for resolution of the issues relevant to compliance with this CID, including but not limited to personnel with knowledge about your information or records management systems, relevant materials such as organizational charts, and samples of material required to be produced. If any issues relate to ESI, you must make available a person familiar with your ESI systems and methods of retrieval.

C. **Applicable Time Period:** Unless otherwise directed in the specifications, the applicable time period for the request shall be from January 1, 2015, until the date of full and complete compliance with this CID.

D. **Claims of Privilege:** If any material called for by this CID is withheld based on a claim of privilege, work product protection, or statutory exemption, or any similar claim (*see* 16 C.F.R. § 2.7(a)(4)), the claim must be asserted no later than the return date of this CID. In addition, pursuant to 16 C.F.R. § 2.11(a)(1), submit, together with the claim, a detailed log of the items withheld. The information in the log shall be of sufficient detail to enable the Commission staff to assess the validity of the claim for each document, including attachments, without disclosing the protected information. Submit the log in a searchable electronic format, and, for each document, including attachments, provide:

1. Document control number(s);

2. The full title (if the withheld material is a document) and the full file name (if the withheld material is in electronic form);

3. A description of the material withheld (for example, a letter, memorandum, or email), including any attachments;

4. The date the material was created;

5. The date the material was sent to each recipient (if different from the date the material was created);

6. The email addresses, if any, or other electronic contact information to the extent used in the document, from which and to which each document was sent;

7. The names, titles, business addresses, email addresses or other electronic contact information, and relevant affiliations of all authors;

8. The names, titles, business addresses, email addresses or other electronic contact information, and relevant affiliations of all recipients of the material;

9. The names, titles, business addresses, email addresses or other electronic contact information, and relevant affiliations of all persons copied on the material;

10. The factual basis supporting the claim that the material is protected; and

11. Any other pertinent information necessary to support the assertion of protected status by operation of law.

16 C.F.R. § 2.11(a)(1)(i)-(xi).

In the log, identify by an asterisk each attorney who is an author, recipient, or person copied on the material. The titles, business addresses, email addresses, and relevant affiliations of all authors, recipients, and persons copied on the material may be provided in a legend appended to the log. However, provide in the log the information required by Instruction D.6. 16 C.F.R. § 2.11(a)(2). The lead attorney or attorney responsible for supervising the review of the material and who made the determination to assert the claim of protected status must attest to the log. 16 C.F.R. § 2.11(a)(1).

If only some portion of any responsive material is privileged, all non-privileged portions of the material must be submitted. Otherwise, produce all responsive information and material without redaction. 16 C.F.R. § 2.11(c). The failure to provide information sufficient to support a claim of protected status may result in denial of the claim. 16 C.F.R. § 2.11(a)(1).

E. **Document Retention:** You shall retain all documentary materials used in the preparation of responses to the specifications of this CID. The Commission may require the submission of additional documents at a later time during this investigation. **Accordingly, you should suspend any routine procedures for document destruction and take other measures to prevent the destruction of documents** that are in any way relevant to this investigation during its pendency, irrespective of whether you believe such documents are protected from discovery by privilege or otherwise. *See* 15 U.S.C. § 50; *see also* 18 U.S.C. §§ 1505, 1519.

F. **Petitions to Limit or Quash:** Any petition to limit or quash this CID must be filed with the Secretary of the Commission no later than twenty (20) days after service of the CID, or, if the return date is less than twenty (20) days after service, prior to the return date. Such petition shall set forth all assertions of protected status or other factual and legal objections to the CID, including all appropriate arguments, affidavits, and other supporting documentation. 16 C.F.R. § 2.10(a)(1). Such petition shall not exceed 5,000 words as set forth in 16 C.F.R. § 2.10(a)(1) and must include the signed separate statement of counsel required by 16 C.F.R. § 2.10(a)(2). **The Commission will not consider petitions to quash or limit absent a pre-filing meet and confer session with Commission staff and, absent extraordinary circumstances, will consider only issues raised during the meet and confer process. 16 C.F.R. § 2.7(k); *see also* § 2.11(b).**

G. **Modification of Specifications:** If you believe that the scope of the required search or response for any specification can be narrowed consistent with the Commission's need for documents or information, you are encouraged to discuss such possible modifications, including any modifications of definitions and instructions, with **Carolyn Hann** at **(202) 326-2745**. All such modifications must be agreed to in writing by the Bureau Director, or a Deputy Bureau Director, Associate Director, Regional Director, or Assistant Regional Director. 16 C.F.R. § 2.7(l).

H. **Certification:** A duly authorized manager of the Company shall certify that the response to this CID is complete. This certification shall be made in the form set out on the back of the CID form, or by a declaration under penalty of perjury as provided by 28 U.S.C. § 1746.

I. **Scope of Search:** This CID covers documents and information in your possession or under your actual or constructive custody or control including, but not limited to, documents and information in the possession, custody, or control of your attorneys, accountants, directors, officers, employees, and other agents and consultants, whether or not such documents and information were received from or disseminated to any person or entity.

J. **Document Production:** You shall produce the documentary material by making all responsive documents available for inspection and copying at your principal place of business. Alternatively, you may elect to send all responsive documents to **Connor Sands**, Federal Trade Commission, **600 Pennsylvania Avenue, NW, CC-10528, Washington, DC 20580**. Because postal delivery to the Commission is subject to delay due to heightened security precautions, please use a courier service such as Federal Express or UPS. Notice of your intended method of production shall be given by email or telephone to **Carolyn Hann** at **chann@ftc.gov** or **(202) 326-2745** at least five days prior to the return date.

K. **Document Identification:** Documents that may be responsive to more than one specification of this CID need not be submitted more than once; however, your response should indicate, for each document submitted, each specification to which the document is responsive. If any documents responsive to this CID have been previously supplied to the Commission, you may comply with this CID by identifying the document(s) previously provided and the date of submission. Documents should be produced in the order in which they appear in your files or as electronically stored and without being manipulated or otherwise rearranged; if documents are removed from their original folders, binders, covers, containers, or electronic source in order to be produced, then the documents shall be identified in a manner so as to clearly specify the folder, binder, cover, container, or electronic media or file paths from which such documents came. In addition, number by page (or file, for those documents produced in native electronic format) all documents in your submission, preferably with a unique Bates identifier, and indicate the total number of documents in your submission.

L. **Production of Copies:** Unless otherwise stated, legible photocopies (or electronically rendered images or digital copies of native electronic files) may be submitted in lieu of original documents, provided that the originals are retained in their state at the time of receipt of this CID. Further, copies of originals may be submitted in lieu of originals only if they are true, correct, and complete copies of the original documents; provided, however, that submission of a copy shall constitute a waiver of any claim as to the authenticity of the copy should it be necessary to introduce such copy into evidence in any Commission proceeding or court of law; and provided further that you shall retain the original documents and produce them to Commission staff upon request. Copies of marketing materials and advertisements shall be produced in color, and copies of other materials shall be produced in color if necessary to interpret them or render them intelligible. A complete copy of each document should be submitted even though only a portion of the document is within the terms of the specification. The document shall not be edited, cut,

or expunged and shall include all covering letters and memoranda, transmittal slips, appendices, tables, or other attachments and all other documents referred to in the document or attachments.

M. **Electronic Submission of Documents:** The following guidelines refer to the production of any ESI or digitally imaged hard copy documents. Before submitting any electronic production, you must confirm with the Commission counsel named above that the proposed formats and media types will be acceptable to the Commission. The FTC requests Concordance load-ready electronic productions, including DAT and OPT load files.

1. ESI: Documents created, utilized, or maintained in electronic format in the ordinary course of business should be delivered to the FTC as follows:

   a. Spreadsheet and presentation programs, including but not limited to Microsoft Access, SQL, and other databases, as well as Microsoft Excel and PowerPoint files, must be produced in native format with extracted text and metadata. Data compilations in Excel spreadsheets, or in delimited text formats, must contain all underlying data un-redacted with all underlying formulas and algorithms intact. All database productions (including structured data document systems) must include a database schema that defines the tables, fields, relationships, views, indexes, packages, procedures, functions, queues, triggers, types, sequences, materialized views, synonyms, database links, directories, Java, XML schemas, and other elements, including the use of any report writers and custom user data interfaces;

   b. All ESI other than those documents described in M.1.a above must be provided in native electronic format with extracted text or Optical Character Recognition (OCR) and all related metadata, and with corresponding image renderings as converted to Group IV, 300 DPI, single-page Tagged Image File Format (TIFF) or as color JPEG images (where color is necessary to interpret the contents);

   c. Each electronic file should be assigned a unique document identifier ("DocID") or Bates reference.

2. Hard Copy Documents: Documents stored in hard copy in the ordinary course of business should be submitted in an electronic format, subject to the following requirements:

   a. The documents should be true, correct, and complete copies of the original documents as converted to TIFF (or color JPEG) images with corresponding document-level OCR text;

   b. Each page shall be endorsed with a document identification number (which can be a Bates number or a document control number);

c. Logical document determination should be clearly rendered in the accompanying load file and should correspond to that of the original document; and

d. Documents shall be produced in color where necessary to interpret them or render them intelligible.

3. For each document electronically submitted to the FTC, include the following metadata fields in a standard ASCII delimited Concordance DAT file:

a. For electronic mail: begin Bates or unique document identification number ("DocID"), end Bates or DocID, mail folder path (location of email in personal folders, subfolders, deleted or sent items), custodian, from, to, cc, bcc, subject, date and time sent, date and time received, and complete attachment identification, including the Bates or DocID of the attachments (AttachIDs) delimited by a semicolon, MD5 or SHA Hash value, and link to native file;

b. For email attachments: begin Bates or DocID, end Bates or DocID, parent email ID (Bates or DocID), page count, custodian, source location/file path, file name, file extension, file size, author, date and time created, date and time modified, date and time printed, MD5 or SHA Hash value, and link to native file;

c. For loose electronic documents (as retrieved directly from network file stores, hard drives, etc.): begin Bates or DocID, end Bates or DocID, page count, custodian, source media, file path, filename, file extension, file size, author, date and time created, date and time modified, date and time printed, MD5 or SHA Hash value, and link to native file;

d. For imaged hard copy documents: begin Bates or DocID, end Bates or DocID, page count, source, and custodian; and where applicable, file folder name, binder name, attachment range, or other such references, as necessary to understand the context of the document as maintained in the ordinary course of business.

4. If you intend to utilize any de-duplication or email threading software or services when collecting or reviewing information that is stored in your computer systems or electronic storage media, or if your computer systems contain or utilize such software, you must contact the Commission counsel named above to determine whether and in what manner you may use such software or services when producing materials in response to this request.

5. Submit electronic productions as follows:

a. With passwords or other document-level encryption removed or otherwise provided to the FTC;

b. As uncompressed electronic volumes on size-appropriate,

Windows-compatible, media;

c. All electronic media shall be scanned for and free of viruses; and

d. Data encryption tools may be employed to protect privileged or other personal or private information. The FTC accepts TrueCrypt, PGP, and SecureZip encrypted media. The passwords should be provided in advance of delivery, under separate cover. Alternate means of encryption should be discussed and approved by FTC counsel.

e. Please mark the exterior of all packages containing electronic media sent through the U.S. Postal Service or other delivery services as follows:

MAGNETIC MEDIA – DO NOT X-RAY
MAY BE OPENED FOR POSTAL INSPECTION.

6. All electronic files and images shall be accompanied by a production transmittal letter which includes:

a. A summary of the number of records and all underlying images, emails, and associated attachments, native files, and databases in the production; and

b. An index that identifies the corresponding consecutive document identification number(s) used to identify each person's documents and, if submitted in paper form, the box number containing such documents. If the index exists as a computer file(s), provide the index both as a printed hard copy and in machine-readable form (provided that the Commission counsel named above determines prior to submission that the machine-readable form would be in a format that allows the agency to use the computer files). The Commission counsel named above will provide a sample index upon request.

A Bureau of Consumer Protection Production Guide is available upon request from the Commission counsel named above. This guide provides detailed directions on how to fully comply with this instruction.

N. **Sensitive Personally Identifiable Information:** If any material called for by these requests contains sensitive personally identifiable information or sensitive health information of any individual, please contact us before sending those materials to discuss whether it would be appropriate to redact the sensitive information. If that information will not be redacted, contact us to discuss encrypting any electronic copies of such material with encryption software such as SecureZip and provide the encryption key in a separate communication.

For purposes of these requests, sensitive personally identifiable information includes: an individual's Social Security number alone; or an individual's name or address or phone number in combination with one or more of the following: date of birth; Social Security number; driver's license number or other state identification number or a foreign country equivalent; passport

number; financial account number; credit card number; or debit card number. Sensitive health information includes medical records and other individually identifiable health information relating to the past, present, or future physical or mental health or conditions of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual.

O. **Information Identification:** Each specification and subspecification of this CID shall be answered separately and fully in writing under oath. All information submitted shall be clearly and precisely identified as to the specification(s) or subspecification(s) to which it is responsive.

P. **Certification of Records of Regularly Conducted Activity:** Attached is a Certification of Records of Regularly Conducted Activity, which may reduce the need to subpoena the Company to testify at future proceedings in order to establish the admissibility of documents produced in response to this CID. You are asked to execute this Certification and provide it with your response.

III. INTERROGATORIES

Demand is made for the following information from the **Company**:

1. State the Company's full legal name, principal address, telephone number, the date and state of incorporation or licensing, and all other names under which the Company has done business.

2. Identify all officers, directors, members, principals, and owners of the Company and all shareholders with five percent or more ownership of the Company, stating each shareholder's percentage of ownership, since the Company was formed.

3. Identify the names, addresses, officers, directors, owners, and states of incorporation of all of the Company's wholly or partially owned subsidiaries, parent companies, unincorporated divisions, joint ventures, partnerships, operations under assumed names, affiliates, and predecessor companies, and describe the relationship of each to the Company.

4. Identify each of the following entities and individuals and describe in detail their corporate or business relationship or other affiliation with the Company:

    a. Lexium International, LLC, including Gentech Pharmaceutical, LLC;

    b. Mary Lirette;

    c. Tara Vest;

    d. Gentech Enterprises, LLC;

    e. Kalos Therapeutics, Inc.;

f. George Colberg;

g. James Merrit, M.D.;

h. Axo International LLC;

i. G&M Estates USA, Inc.;

j. RNCG Angel Foundation, Inc.;

k. WeVets, LLC d/b/a WeVets.us; and

l. Worldwide Cancer Research.

5. State the following information for every product manufactured, marketed, offered for sale, sold, or distributed by you since January 1, 2015, under, or in connection with, the Company's name, copyright, trademark, or other identifying information:

a. The name and a description of the nature of the product;

b. The date when the product was first manufactured, marketed, and sold by you;

c. The manufacturer of the product; and

d. The supplier for each product or ingredient supplied to the Company by any third party.

6. Identify each person responsible for ensuring that each CellMark Product is manufactured, packaged, and labeled as specified in the master manufacturing record (established pursuant to 21 C.F.R. §§ 111.205 & 111.210).

7. Identify each component, including dietary ingredients, used in the manufacture of each CellMark Product. For each component used in the manufacture of such CellMark Product, state the identity specifications (established pursuant to 21 C.F.R. § 111.70(b)(1)) and the component specifications (established pursuant to 21 C.F.R. § 111.70(b)(2)) to ensure that the strength and composition of the components in such CellMark Product were met.

8. State the product specification (as defined in Definition T, above) of each CellMark Product.

9. If you received any CellMark Products from a supplier for packaging or labeling, state the product specifications (as defined in Definition T, above) established to provide assurance that such CellMark Products are adequately identified and consistent with your purchase order.

10. For each certificate of analysis provided by a supplier, state the steps taken to qualify the supplier by establishing the reliability of the supplier's certificate of analysis through

confirmation of the results of the supplier's tests or examinations and the basis for qualification of the supplier.

11. Specify the steps you have taken to ensure that the tests and examinations that you have used to determine whether the specifications as specified in the master manufacturing record (established pursuant to 21 C.F.R. §§ 111.205 & 111.210) for each CellMark Product are met are appropriate, scientifically valid methods.

12. Identify the manufacturer of each CellMark Product and the supplier of each dietary ingredient or component used in the manufacture of such CellMark Product.

13. State the steps you have taken to identify and use an appropriate scientifically valid method for each specification established pursuant to 21 C.F.R. § 111.320(b) for which testing or examination is required to determine whether the applicable specification is met.

14. With respect to each CellMark Product, state:

    a. The per unit wholesale price;

    b. The per unit retail price;

    c. The number of units sold at wholesale in 2015 and 2016 to date;

    d. The number of units sold at retail in 2015 and 2016 to date;

    e. The total dollar amount provided in refunds to consumers in 2015 and 2016 to date;

    f. The total dollar amount spent by the Company on advertising, marketing, or other promotion during 2015 and 2016 to date; and

    g. The total dollar amount spent by the Company on research and development during 2015 and 2016 to date.

If you maintain financial data on a fiscal schedule that differs from the calendar year schedule, provide this data according to those fiscal years and identify the dates of the fiscal year.

15. For each advertisement and promotional material produced in response to Document Specification 3, state the beginning and ending dates of dissemination, and the dates, times, and locations the ads were disseminated. For print ads and press releases, specify every publication, date, and community of dissemination; for television, radio, or Internet radio ads, provide every network, system or station, date, and community of dissemination; for Internet ads, specify every URL, date, and number of hits or visits; for all other materials, provide sufficient information to permit a determination of how many items were disseminated, when, where, and to whom.

16. State the full name and URL for each website operated by or on behalf of the Company, or affiliated entities or individuals, that describes, discusses, promotes, advertises, or sells any CellMark Product.

17. State any keywords, terms, phrases, or other criteria that the Company (or any person or entity acting for or on behalf of the company) has used to effect the placement or delivery of any advertisement or sponsored link for each CellMark Product in connection with any online advertising network or advertisement delivery or contextual marketing software or system, including, but not limited to, the placement or delivery of any advertisement or sponsored link in search results generated by Google or any other Internet search engine (*e.g.*, through the Google AdWords program).

18. For each advertisement requested in Document Specification 3, identify each person presented as a user of the products or providing a consumer testimonial for such products, and provide the following information for each individual. Your response should include, but not be limited to, the following individual: Sue Haberkorn.

    a. Whether that individual is or was a purchaser of the CellMark Product;

    b. The product(s) purchased by that consumer, the date(s) of the purchase, and the total amount of purchases by that consumer;

    c. The circumstances under which the results given in the testimonial were achieved, including, but not limited to: (i) describing whether the individual was seeking medical treatment or advice at the time of using the product, and if so, identifying the source of treatment or advice; and (ii) describing whether the individual was using other medications or supplements at the time of using the product, and if so, identifying the other medications or supplements;

    d. The process the Company used to confirm that the individual actually achieved the reported results as represented in the advertisement.

    e. Whether the individual was compensated for appearing in the advertisement(s), and if so, state the amount of compensation;

    f. Whether the individual was compensated by the Company on an ongoing basis (*e.g.*, salary, royalty, promotion payments) and if so, state the amounts paid and schedule or dates of payment; and

    g. The individual's relationship to the Company or any consultant, shareholder, officer, or employee of the Company.

19. Describe in detail the process, procedures, guidelines, or standards that the Company followed in determining whether or not to post product reviews and satisfaction scores submitted by consumers via any of the Company's websites, including store.cellmarkbiopharma.com.

20. State the full domain name for each website operated by or on behalf of the Company, including any website that has described, discussed, promoted, advertised, offered for sale or sold any CellMark Products, or directly linked to store.cellmarkbiopharma.com. For each such website, identify the domain name registrant.

21. To the extent not already provided in response to another Specification of this CID, identify any and all domain names for which Derek Vest is the registrant.

22. Regardless of time period, identify each retailer, affiliate, distributor, physician, or other person responsible for selling or distributing any CellMark Products. For each such entity or person, state the following:

    a. The manner of sale or distribution;

    b. The full domain names and URLs of any websites through which such entity or individual advertises or sells any CellMark Products;

    c. The total gross sales of CellMark Products by year; and

    d. The manner in which such entity or individual is compensated for sales of any CellMark Products.

23. State the full name and URLs of all bloggers contacted, recruited, or hired by the Company or by any person, company, agency, or other entity working for or on behalf of the Company, in connection with any advertising or promotional campaign regarding any CellMark Product.

24. Identify all affiliate marketers and affiliate marketing networks hired by the Company or by any person, company, agency, or other entity working for or on behalf of the Company, in connection with any advertising or promotional campaign regarding any CellMark Product, and for each also provide the URL of any websites used by the affiliate to promote any of the products, and the total amount of compensation paid by the company to the affiliate to date.

25. Identify each person, company, agency, or other entity with responsibility for creating, designing, developing, reviewing, testing, evaluating, or approving any advertisement or promotional material submitted in response to Document Specification 3, and give a brief description of the functions performed by each.

26. Without regard to time period, identify each person who participated in the development, formulation, research, or testing of any CellMark Product and describe in detail the specific work performed by each, the time period when they performed such work, and any compensation, remuneration, or thing of value provided to such person.

27. Without regard to time period, identify each academic institution, research facility, research organization, or other entity that participated in the development, formulation, research, or testing of any CellMark Product, and describe in detail the specific work

performed by each, the time period when the entity performed such work, and any compensation, remuneration, or thing of value provided to such entity.

28. For any study produced in response to Document Specification 9, state the exact ingredients and the amount of each ingredient used in the study. In addition, state the source of each ingredient.

29. Without regard to time period, identify each person, company, agency, or other entity with responsibility for developing, reviewing, or evaluating substantiation, scientific or otherwise, for representations made in any advertisement or promotional material submitted in response to Document Specification 3, and give a brief description of the functions performed by each.

30. Describe in detail the process, procedures, guidelines, or standards that the Company followed during the applicable time period in determining whether or not to approve the dissemination of advertisements for any CellMark Product, and identify the individual(s) responsible for formulating such procedures, guidelines, or standards, and the individual(s) responsible for approving such ads prior to dissemination.

31. Without regard to time period, identify all experts consulted by the Company or by any ad agency acting on behalf of the Company, or upon whose advice, opinion, or expertise the Company, or any ad agency acting on behalf of the Company, relied on to substantiate or refute the express or implied claims set forth in Document Specification 7.

32. For each of the following persons, without regard to time period, describe any current or previous scientific research, business, or other relationship or affiliation with you, state the dates during which such relationship or affiliation took place, and state any compensation, remuneration, or thing of value provided to that person:

    a. Dr. Stan Headley;

    b. Erika Boliek; and

    c. Anthony Spotora.

33. For each of the following persons, without regard to time period, provide all information about his or her college, graduate school, and post-graduate educations, including dates degrees were obtained, names of degrees (*e.g.*, B.A., M.A., M.D., Ph.D.), and majors or specializations; beginning and ending months and years of employment; positions held; and citations to publications:

    a. Derek Vest;

    b. Erika Boliek;

    c. Anthony Spotora; and

d. Dr. Stan Headley.

34. Describe the company's policies with regard to how and when consumers are placed into or become part of any continuity program or negative option.

35. Describe the company's policies with regard to how and when consumers may cancel their participation in any continuity program or negative option, and how and when consumers receive refunds for CellMark Products, including but not limited to any requirements, limits, or conditions relating to: time period, restocking fees, obtaining return merchandise authorization codes, and returning opened or unused product.

36. Identify each person or entity responsible for fulfilling consumers' orders of CellMark Product and provide the following information:

    a. Describe all procedures for obtaining, recording, and preserving consumers' records of ordering or authorizing the shipment of CellMark Product;

    b. State the location(s) of such records; and

    c. Identify the custodian(s) of such records.

37. Identify each person or entity responsible for customer service issues, refund requests, and consumer complaints regarding CellMark Products and provide the following information:

    a. Describe all procedures for handling, recording, and preserving records concerning customer service issues, refund requests, and consumer complaints;

    b. State the location(s) of such records; and

    c. Identify the custodian(s) of such records.

38. Identify each consumer who filed a complaint or requested a refund relating to CellMark Product. For each consumer, describe the complaint or the amount of refund requested, and state what, if anything, was the company's response.

39. State, as of the last day of each quarterly period from January 1, 2015 through the present:

    a. The number of active accounts of consumers who purchased any CellMark Products;

    b. The number of active accounts of consumers who purchased any CellMark Products where the purchaser was ever enrolled in a continuity program or negative option; and

    c. The number of closed accounts of consumers who purchased any CellMark Products.

40. State the number of accounts of consumers who purchased any CellMark Products that have experienced one or more:

    a. Chargebacks;

    b. Refunds; and

    c. Returns of any CellMark Products rejected by consumers as unordered.

41. Without regard to time period, identify all lawsuits or legal proceedings filed against the Company or otherwise involving the Company's advertising, marketing, and sales practices relating to any CellMark Products. Include in your identification the names of all parties, the jurisdiction in which the matter is or was pending, the case number, the date filed, the identity of counsel for all parties, and the current status or disposition of the matter.

42. Identify all persons at the Company who participated in preparing responses to this CID.

43. If, for any Document Specification in this CID, documents that would have been responsive were destroyed, mislaid, transferred, deleted, altered, or overwritten:

    a. Describe in detail the document;

    b. State the date such document was destroyed, mislaid, transferred, deleted, altered, or overwritten;

    c. Describe the circumstance under which such document was destroyed, mislaid, transferred, deleted, altered, or overwritten; and

    d. Identify the person authorizing such action.

IV. DOCUMENTS

Demand is made for the following documents and things:

1. A copy of each organization chart and personnel directory for the Company, including email addresses, in effect since January 1, 2015.

2. Two packages, in their original packaging, of each version of every formulation of CellMark Products manufactured, marketed, offered for sale, sold, or distributed by you, or by any affiliated company.

3. A copy of every advertisement for each CellMark Product disseminated on or after January 1, 2015. Your response should include, but not be limited to, package labeling, package inserts, web pages (including metatags used for the purpose of search engine optimization or otherwise directing web traffic), user manuals or handbooks, customer support materials, promotional materials, and marketing materials, that have been disseminated to consumers, distributors or potential distributors (including Internet distributors), retailers, or any other person since January 1, 2015, or that have been prepared for future dissemination or use.

4. All marketing or advertising plans for each CellMark Product, including, but not limited to, materials about advertising and marketing strategies, themes, or concepts; media recommendations, strategies, and plans; and marketing reports, business studies, and creative strategies relating to approaches for advertising, marketing, or promoting each of the CellMark Products, whether or not actually implemented.

5. All communications between the Company and any advertising agency, advertising placement agency, or network marketing agency that participated in the creation, production, or dissemination of any advertisement for each CellMark Product.

6. All documents relating to any communications between the Company or any ad agency acting on the Company's behalf, and any magazine or newspaper publisher, television or radio network, Internet radio platform, or any other media outlet concerning any claims, messages, or communications in any proposed or disseminated advertisement or promotional material for any CellMark Products.

7. To the extent not already provided in response to another Specification of this CID, all marketing or consumer research relating to each CellMark Product.

8. Regardless of whether the Company believes these claims were made in advertising or promotional materials, and without regard to time period, all documents, including but not limited to, studies, tests, experiments, demonstrations, and written or oral statements or opinions, whether or not completed or published, substantiating each of the following claims:

    a. Cognify treats, cures, mitigates, or prevents cognitive dysfunction caused by chemotherapy ("chemo brain"), including Mild Cognitive Impairment;

b. Cognify treats, cures, mitigates, or prevents chemo brain symptoms including memory loss regarding names, places, dates, or appointments, difficulty finding the right word for common objects, and trouble concentrating or focusing;

c. Cognify is specifically formulated to alleviate chemo brain symptoms;

d. Cognify repairs brain tissue, reduces inflammation, increases neurotransmitters, and stimulates the growth of new brain cells;

e. Cognify is a "pharmaceutical grade" dietary supplement;

f. Cognify is clinically proven to prevent chemo brain;

g. CellAssure is specifically formulated to meet the nutritional needs of cancer patients undergoing treatment including surgery, radiation, chemotherapy, and nutritional turmoil;

h. CellAssure was formulated based on direct requests from physicians, dietitians, and cancer patients;

i. CellAssure is clinically proven to meet the nutritional needs of cancer patients undergoing chemotherapy; and

j. CellAssure is clinically proven to exhibit anti-cancer and anti-tumor properties, mitigate anemia, improve liver functions, and help reduce inflammation and pain.

9. All other documents, without regard to time period, not produced in response to Document Specification 8, relating to substantiation for the claims listed in Document Specification 8, including, but not limited to, documents that tend to call into question or disprove any of those claims, and documents that question the existence of substantiation for those claims.

10. All documents, without regard to time period, relating to any study conducted or sponsored by the Company, or the supplier of any active ingredients in any CellMark Products, examining the effectiveness of each of the CellMark Products, or any active ingredient in the CellMark Products, for the claims listed in Document Specification 8 above, whether or not the study was completed or published, including, but not limited to:

a. All reports, articles, write-ups, or other accounts of the results of the study, and drafts of such documents reviewed by the study sponsor or any other person not employed by the research entity;

b. All final protocols and amendments to such protocols;

c. All documents relating to recruitment; randomization; instructions, including oral instructions, to participants; and subject compliance;

d. All raw data collected from participants enrolled in the study, including any participants who did not complete the study; source documents for such data; data dictionaries; and case report forms;

e. Documents sufficient to identify all study participants, including any participants who did not complete the study, and all communications with any participants relating to the study;

f. All documents relating to any statistical analysis of any study data, including, but not limited to, any pretest analysis, intent-to-treat analysis, or between-group analysis performed on any study data;

g. All documents relating to attempts to publish articles or other publications based on the data from the study; and

h. All documents relating to the sponsorship of the study, including all communications, including contracts, between any sponsor and the study's researchers.

11. All documents sufficient to show the product specification (as defined in Definition T, above) of each CellMark Product.

12. All documents, including tests and examinations, sufficient to show, that each CellMark Product meets all product specifications (as defined in Definition T, above) as established in the master manufacturing record (pursuant to 21 C.F.R. §§ 111.205 & 111.210) for such CellMark Product.

13. A copy of each master manufacturing record (established pursuant to 21 C.F.R. §§ 111.205 & 111.210) for each CellMark Product.

14. If you received any CellMark Products from a supplier or manufacturer, all documents showing the means established to assure that such CellMark Product meets product specifications (as defined in Definition T, above) consistent with your purchase order.

15. All documents referring or relating to any tests or examinations, including results, conducted to confirm the identity, strength, or composition of any dietary ingredient contained in each CellMark Product.

16. For components that are not dietary ingredients, all documents referring or relating to any tests or examinations conducted to confirm the identity of those components or to determine whether those components comply with component specifications (as established pursuant to 21 C.F.R. 111.70(b)(2)).

17. For components that are not dietary ingredients, all documents referring or relating to any certificate of analysis from the supplier of the component.

18. All documents sufficient to show your qualification of any supplier for the purpose of relying on the supplier's certificate of analysis.

19. All documents referring or relating to your verification of the laboratory examination and testing methodologies used to determine whether any CellMark Products meet all product specifications (as defined in Definition S, above).

20. All documents referring or relating to consumer testimonials or expert endorsements for any of the CellMark Products, including, but not limited to, communications, contracts, and agreements between you and any person providing a testimonial or endorsement, compensation paid to such person, and any documents provided to expert endorsers prior to use of their endorsement.

21. If such documents exist, all curricula vitae ("CVs") or resumes for Derek Vest, Erika Boliek, Anthony Sporota, and Dr. Stan Headley, without regard to time period.

22. All documents, without regard to time period, relating to the Company's decision to market or sell any of the CellMark Products as part of a continuity plan or negative option, including, but not limited to, emails, memos, market research, studies, reports, analyses, or surveys about consumer attitudes, beliefs, or understanding about any continuity program or negative option.

23. All documents, without regard to time period, relating to the Company's refund policies or practices.

24. All documents used in preparation for or during communications with any consumer, including scripts, outlines, guides, suggested responses to questions, policies, manuals, or procedures for handling consumer product requests and consumer complaints and inquiries, including communications about any continuity program or negative option, and refund or cancelation policies.

25. All documents, without regard to time period, relating to any communications concerning:

    a. Contracts or agreements;

    b. Payments requested or received;

    c. Consumers; or

    d. Returns, refunds, or chargebacks

between the Company and any entities or individuals responsible for: shipping, handling or fulfilling orders; handling customer service; providing websites or arranging for the providing of websites; addressing any consumer complaints; returns; refunds; or chargeback requests for any CellMark Products.

26. All documents referring or relating to communications between sales or customer service representatives, working for the Company or on the Company's behalf, and consumers who purchased or were interested in purchasing CellMark Products, including:

    a. Recordings of telephone calls;

    b. Notes taken during or after telephone calls;

    c. Online chat transcripts; and

    d. Correspondence.

27. All documents and communications referring or relating to consumer complaints that they or a family member:

    a. Never authorized or made more than a single purchase of the CellMark Product;

    b. Never ordered the CellMark Product;

    c. Canceled or wanted to cancel their order for the CellMark Product;

    d. Were billed for a shipment of the CellMark Product that was returned;

    e. Were billed for CellMark Products that were never ordered;

    f. Were billed for CellMark Products that were never received;

    g. Were billed for a CellMark Product that was sent or received after the account was canceled;

    h. Did not understand that they would be receiving automatic shipments of the CellMark Product unless they took a specific action to cancel future shipments;

    i. Did not authorize the company to interpret their failure to affirmatively cancel future shipments of the CellMark Product as their acceptance of such shipments; or

    j. Were subject to improper, deceptive, or abusive debt collection practices.

28. To the extent not already provided in response to another Specification of this CID, all documents referring or relating to consumer complaints concerning the CellMark Products, including any communications between the Company and any affiliated person or entity and any consumer or any medical professional concerning any consumer injury or other adverse event relating to the use of the CellMark Products.

29. All documents relating to any communications between the Company or any affiliated entity or ad agency, and any company, website, blog, or organization that reviews or

evaluates consumer products, concerning the use or performance of the CellMark Products.

30. All documents or communications received from or provided to any government agency, Better Business Bureau office, or consumer protection organization relating to consumer complaints about the CellMark Products and any continuity program or negative option, and any documents, charts, or other materials summarizing, analyzing, or discussing such complaints.

31. All documents referring or relating to any communications between you, or any affiliated person or entity, and the National Advertising Division of the Council of Better Business Bureaus or the Electronic Retailing Self-Regulation Program concerning any advertising for CellMark Products.

32. All documents referring or relating to any communication between the Company or any affiliated person or entity and the Food and Drug Administration concerning any CellMark Products.

33. All complaints and answers in any state or federal court litigation, initiated since January 1, 2015 or currently pending, in which the Company or any affiliated person or entity, is named as a defendant, and that relates or refers to CellMark Products.

34. All documents referring or relating to any communications between you, or any affiliated person or entity, and any non-profit or charity organization including, but not limited to, RNCG Angel Foundation, Inc., WeVets, LLC d/b/a WeVets.us, and Worldwide Cancer Research relating to you or any CellMark Products.

CERTIFICATION OF RECORDS OF REGULARLY CONDUCTED ACTIVITY
Pursuant to 28 U.S.C. § 1746

1. I, _____, have personal knowledge of the facts set forth below and am competent to testify as follows:

2. I have authority to certify the authenticity of the records produced by CellMark Biopharma LLC and attached hereto.

3. The documents produced and attached hereto by CellMark Biopharma LLC are originals or true copies of records of regularly conducted activity that:

   a) Were made at or near the time of the occurrence of the matters set forth by, or from information transmitted by, a person with knowledge of those matters;

   b) Were kept in the course of the regularly conducted activity of CellMark Biopharma LLC; and

   c) Were made by the regularly conducted activity as a regular practice of CellMark Biopharma LLC.

I certify under penalty of perjury that the foregoing is true and correct.

Executed on _____, 2016.

_____
Signature

EXHIBIT 2

2110 First Street, Suite 3-137
Fort Myers, Florida 33901
239/461-2200
239/461-2219 (Fax)

35 SE 1st Avenue, Suite 300
Ocala, Florida 34471
352/547-3600
352/547-3623 (Fax)

U.S. Department of Justice
United States Attorney
Middle District of Florida

Main Office
400 North Tampa Street, Suite 3200
Tampa, Florida 33602
813/274-6000
813/274-6358 (Fax)

300 N. Hogan Street, Suite 700
Jacksonville, Florida 32202
904/301-6300
904/301-6310 (Fax)

400 West Washington Street, Suite 3100
Orlando, Florida 32801
407/648-7500
407/648-7643 (Fax)

Reply to: Fort Myers, FL

March 21, 2016

Derek Vest
11561 Isle Of Palm Drive
Fort Myers Beach, Florida 33931

Re: Grand Jury Investigation
USAO No. 2014R00530

Dear Mr. Vest:

This letter is to advise you that you are now a target of a Federal Grand Jury investigation in this District into introducing and delivering for introduction into interstate commerce misbranded drugs and other matters, and possible violations of federal criminal laws. The United States is prepared to proceed before a Federal Grand Jury to seek charges against you.

Before we proceed to bring these formal charges against you, we would like to discuss the matter with you and your attorney. Please have your attorney contact me as soon as possible at (239) 461-2200 so that we may schedule an appointment. If you do not have an attorney and believe you cannot afford to employ an attorney, you may call me yourself.

If we do not hear from you or your attorney on or before April 6, 2016, we shall assume that you do not wish to discuss the matter and will proceed accordingly.

Sincerely,

A. LEE BENTLEY, III
United States Attorney

By: Yolande G. Viacava
Yolande G. Viacava
Assistant United States Attorney