

ONE HUNDRED TWELFTH CONGRESS
Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
Minority (202) 225-3641

October 22, 2012

Mr. Paul Cirel, Esq.
On behalf of
New England Compounding Center
697 Waverly Street
Framingham, MA 01702

Dear Mr. Cirel:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee is investigating the facts surrounding the recent outbreak of fungal meningitis linked to contaminated steroids made and distributed by the New England Compounding Center (NECC) and the Food and Drug Administration (FDA) oversight of this firm. We are following up on our letter dated October 11, 2012, (see attached) in which we requested that the NECC preserve all relevant documents and communications. In addition, we requested that the NECC make arrangements with Committee staff to schedule a briefing to occur no later than October 18, 2012.

The NECC has failed to provide the requested briefing. On the morning of October 17, 2012, the day after agents from FDA, along with local authorities, raided the NECC's Framingham, Massachusetts, facility, personal counsel for Mr. Barry Cadden – who, until recently, was an owner, President, and Director of Pharmacy at NECC – informed Committee staff that, while Mr. Cadden was not invoking his rights under the Fifth Amendment, he would not be speaking with the Committee at this time. Committee staff then contacted you, as counsel to the NECC, to determine whether the company would comply with the Committee's request for a briefing to occur no later than October 18, 2012. While we are disappointed that the NECC was not able to comply with our briefing request by October 18, the Committee must proceed with the investigation. We expect that your client will cooperate in this matter.

As of today, the Centers for Disease Control and Prevention (CDC) has confirmed that 23 people have died and 297 people have been sickened in 16 States after receiving tainted injections. While the majority of reported cases of meningitis have been linked with one type of

sterile injectable product, preservative-free methylprednisolone acetate, two other products made and distributed by the NECC have now been potentially associated with serious infections.

On September 23, 2004, investigators from the FDA and the Massachusetts Board of Registration in Pharmacy (Board of Pharmacy) inspected the NECC. The inspection was completed on January 19, 2005. On December 4, 2006, the FDA sent the NECC a warning letter detailing significant violations of the Food, Drug, and Cosmetic Act (FDCA) witnessed by the investigators.¹ Included in the list of violations was the NECC's manipulation of a sterile injectable product, which caused FDA to be "especially concerned about potential microbial contamination."² FDA's warning letter informed the NECC that "[f]ailure to promptly correct these deviations may result in additional regulatory action without further notice, including seizure and injunction against you and your firm."³ During initial discussions with Committee staff on October 12, 2012, FDA officials could not confirm whether the agency conducted any follow-up inspections. However, they informed Committee staff that the NECC corresponded with the FDA about a month after the warning letter and assured regulators that the firm was in compliance with good compounding practices.

The joint FDA and State inspection of the NECC's Framingham facility initiated at the end of 2004 was not the first such inspection. On October 18, 2012, Massachusetts public health officials informed Committee staff that a joint inspection of the NECC was also conducted in 2002 and 2003, based in part on an adverse event reported via FDA's MedWatch system. This event was associated with the methylprednisolone product implicated in the recent outbreak. According to a January 10, 2006, consent agreement between the NECC and the Massachusetts Board of Pharmacy,⁴ "this Agreement is in settlement of complaints relating to an adverse complaint report investigated by the United States Food and Drug Administration for methylprednisolone acetate preservative free 80 mg/ml suspension"

The Committee is investigating the facts and circumstances surrounding these inspections, any corrective actions taken and communicated by the NECC to State and Federal regulators after these inspections, and how any such changes were validated by these authorities.

In addition, reports of the NECC's actions with regard to methylprednisolone, as well as other activities observed during these inspections, call into question whether the NECC was operating as a traditional compounding pharmacy or on a commercial scale as a drug manufacturer. The NECC reportedly produced and shipped, at times in bulk, over 17,000 vials of methylprednisolone acetate to 76 different facilities in 23 States, without individual prescriptions for each order. The Committee seeks to determine how long the NECC has been operating in this manner and why, six years after FDA's warning letter and ten years after an inspection relating to methylprednisolone acetate produced and distributed by the NECC, the company was able to continue to do so.

¹ Warning Letter from Gail Costello, Dist. Dir., New England Dist. Office, U.S. Food and Drug Admin., to Barry J. Cadden, Dir. of Pharmacy and Owner, New England Compounding Center (Dec. 4, 2006), *available at* <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm076196.htm>.

² *Id.* at 3.

³ *Id.* at 4.

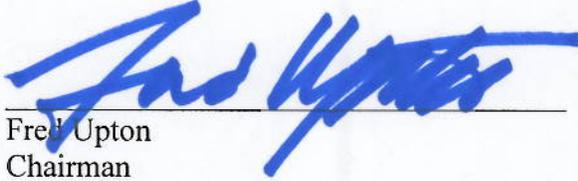
⁴ See attachment.

To assist the Committee in its efforts, please provide the following documents, from January 1, 2002, to the present, by no later than November 5, 2012:

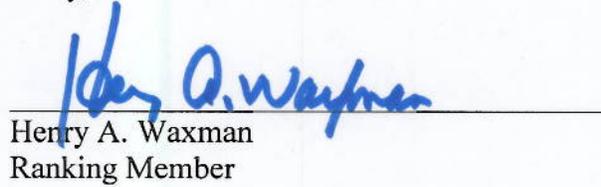
1. All State, Federal, or third party inspection reports (including attachments and exhibits) referring or relating to any facilities owned or operated by the NECC, Ameridose, and/or Alaunus, and all responses to such reports;
2. All consent agreements or other compliance arrangements entered into with State or Federal authorities, as well as any other assurances of compliance provided to these authorities, and all documents and correspondence related to these arrangement or agreements;
3. All documents containing communications between or among any employee, agent, advisor, or representative of the NECC, Ameridose, and/or Alaunus; the FDA; the Massachusetts Board of Pharmacy or other State entities; and any third-party inspectors, referring or relating to any inspections and/or issues with compliance or safety;
4. All documents relating to analysis, assessment, or discussion of quality and safety of methylprednisolone acetate injections produced, prepared, packaged, stored, or distributed at or by the NECC, Ameridose, and/or Alaunus;
5. Copies of all marketing materials or solicitations sent to medical professionals or facilities, or other individuals and entities involved in the distribution or use of products produced, prepared, packaged, stored, or distributed at or by the NECC, Ameridose, and/or Alaunus, and all communications between or among NECC, Ameridose, or Alaunus officials related to these marketing materials or solicitations;
6. All internal policy, procedural documents, manuals, or guidance dated and/or produced, referring or relating to the production, sale, and distribution of drug products by the NECC, Ameridose, and/or Alaunus, including, but not limited to, the solicitation of orders; the link between prescriptions received and the products being produced and distributed; and standards in place to ensure compliance with State and Federal regulations;
7. All documents containing communications between or among any employee, agent, advisor, or representative of the NECC, Ameridose, and/or Alaunus, referring or relating to the manner and/or scope of production, sale, or distribution of drug products.

An attachment to this letter provides additional information about how to respond to the Committee's request. If you have any questions considering this request, please contact John Stone with the Committee staff at (202) 225-2927.

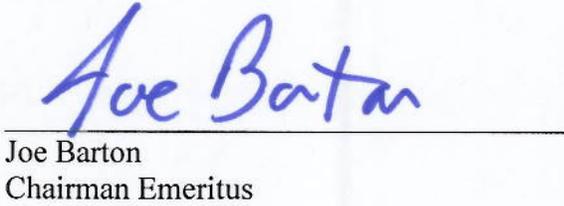
Sincerely,



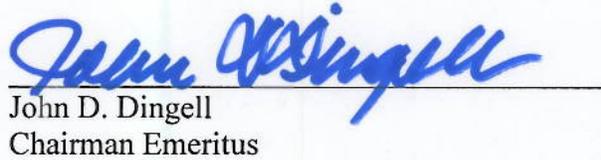
Fred Upton
Chairman



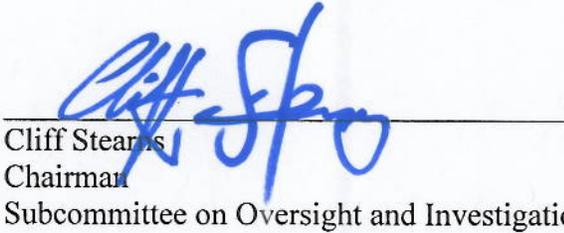
Henry A. Waxman
Ranking Member



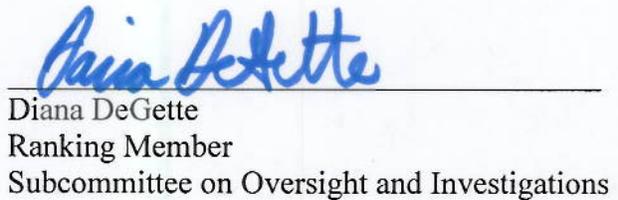
Joe Barton
Chairman Emeritus



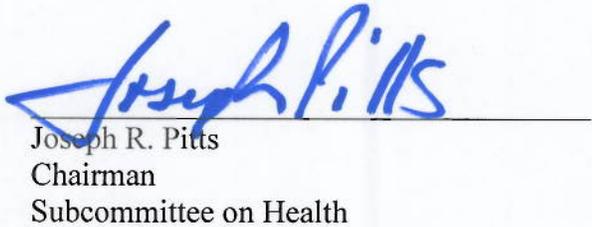
John D. Dingell
Chairman Emeritus



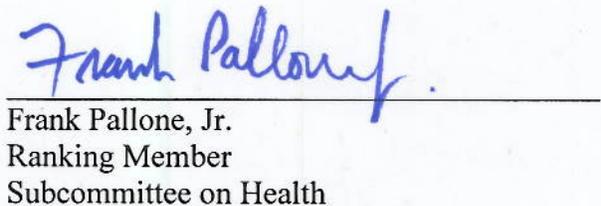
Cliff Stearns
Chairman
Subcommittee on Oversight and Investigations



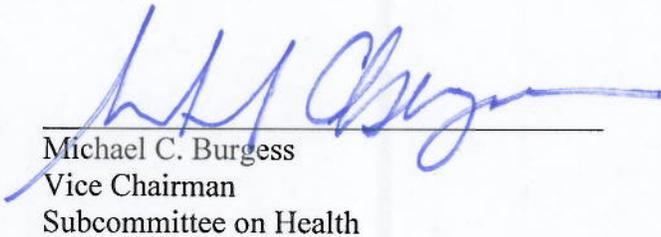
Diana DeGette
Ranking Member
Subcommittee on Oversight and Investigations



Joseph R. Pitts
Chairman
Subcommittee on Health



Frank Pallone, Jr.
Ranking Member
Subcommittee on Health



Michael C. Burgess
Vice Chairman
Subcommittee on Health

Attachments

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED TWELFTH CONGRESS
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COMMITTEE ON ENERGY AND COMMERCE
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October 11, 2012

Mr. Barry J. Cadden
Director of Pharmacy and Owner
New England Compounding Center
697 Waverly Street
Framingham, MA 01702

Dear Mr. Cadden:

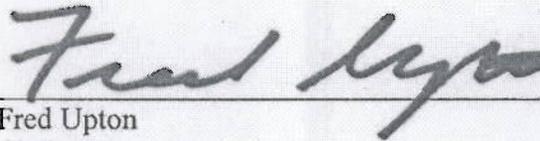
Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee is examining the facts surrounding the recent outbreak of fungal meningitis linked to contaminated spinal steroid injections. Federal officials have linked the contaminated steroid to the New England Compounding Center (NECC) in Framingham, Massachusetts.

As of October 9, 2012, the Centers for Disease Control and Prevention (CDC) announced that eleven people have died and 119 people have been sickened across nine states. CDC also confirmed that the number of cases may rise in the coming weeks given that 13,000 patients have been injected with the drug product compounded and distributed by the NECC.

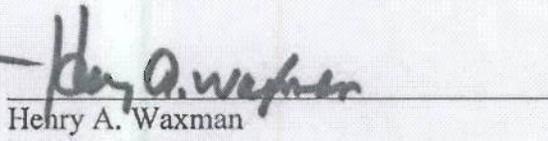
The Committee has a long bipartisan history of conducting drug safety oversight and is very concerned about these recent developments. We will be meeting with FDA, CDC and others that may provide insight into the details surrounding this outbreak and the prevention of future outbreaks. Given this continued interest, we ask that you preserve all documents and communications that may be relevant to understanding how the product was contaminated and distributed as well as the business practices of the NECC in general. In addition, we ask that you make arrangements with Committee staff to schedule a briefing on these matters to occur no later than October 18, 2012.

If you have any questions considering this request, please contact John Stone with the Committee staff at (202) 225-2927.

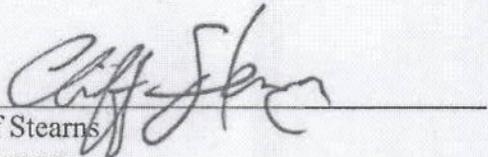
Sincerely,



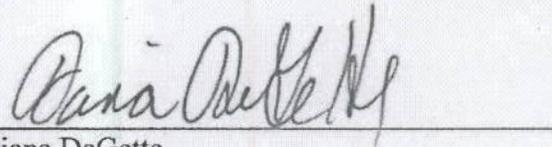
Fred Upton
Chairman



Henry A. Waxman
Ranking Member



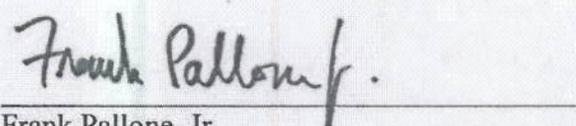
Cliff Stearns
Chairman
Subcommittee on Oversight and Investigations



Diana DeGette
Ranking Member
Subcommittee on Oversight and Investigations



Joseph Pitts
Chairman
Subcommittee on Health



Frank Pallone, Jr
Ranking Member
Subcommittee on Health



Michael C. Burgess
Vice Chairman
Subcommittee on Health

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION
IN PHARMACY

In the Matter of
NEW ENGLAND
COMPOUNDING CENTER
Registration No. [REDACTED]
BARRY J. CADDEN, R.Ph.
License No. [REDACTED]

Docket Nos. DS-03-055
PH-03-066
DS-05-040

CONSENT AGREEMENT

The Board of Registration in Pharmacy ("Board") and NEW ENGLAND COMPOUNDING CENTER ("NECC") (Pharmacy Registration No. [REDACTED]), located at 697 Waverly Road, in Framingham, Massachusetts ("Registrant"), and BARRY J. CADDEN, R.Ph. ("Licensee") Pharmacist License No. [REDACTED] and Manager of Record of Registrant, do hereby stipulate and agree that the following information shall be entered into and become a permanent part of the files of Registrant and Licensee which are maintained by the Board:

1. The parties enter into this Consent Agreement ("Agreement") to resolve disputed matters arising out of the complaints pending against Registrant and Licensee, respectively, as Docket Nos. DS-03-055, PH-03-066 and DS-05-040 ("Complaints").
2. The Registrant, Licensee and the Board stipulate and agree that this Agreement is in settlement of complaints relating to an adverse event complaint report investigated by the United States Food and Drug Administration for methyprednisolone acetate preservative free 80 mg/ml suspension, and concerning the dispensing of Trypan Blue without a valid prescription ("the Complaints").
3. The Registrant, Licensee and the Board acknowledge that this Agreement is a nondisciplinary agreement not reported to the National Association of State Boards of Pharmacy or other outside report agencies, except that the Licensee's failure to fulfill the requirements of paragraph 5 may result in the imposition of discipline by the Board.
4. In order to resolve these matters without further proceedings before the Board, the Registrant, the Licensee, and the Board agree that on the date of the execution of this Agreement by the Board ("Effective Date") the Board will order that the Licensee be placed on Probation for a Period of One (1) Year, and the probation order will be

Stayed for one (1) year from the Effective Date of this Agreement ("the Stay").

5. The Registrant and the Licensee agree as follows:

(a) Within 45 days from the Effective Date of this Agreement, the Registrant and Licensee shall provide documentation satisfactory to the Board that Board-approved evaluator: Pharmacy Support, Inc. ("PST" or "Evaluator"), at the expense of the Registrant and Licensee, has conducted an inspection of and prepared a written report analyzing Registrant's compounding practices and compliance with United States Pharmacopeia Standard 795 - Non-Sterile Compounding Procedures and USP Standard 797 - Sterile Compounding Procedures, in accordance with 247 CMR 9.01(3) ("USP Standards"), with any recommendations for revisions to practice for compliance with USP Standards ("the First Report"). The inspection shall include consideration of, but not be limited to:

- i. Sterile Environmental Design
- ii. Quality Assurance Program
- iii. Media Fills (operator qualification/process validation)
- iv. Environmental Monitoring
- v. Cleaning and Sanitizing Program
- vi. Training Records
- vii. Process Control
- viii. Equipment
- ix. Finished Preparation Testing
- x. Adverse Event Records

(b) The Registrant and Licensee will arrange for the Evaluator to provide a copy of the First Report as described in Paragraph 5(a) directly to the Board within fourteen days of the inspection.

(c) The Registrant and Licensee will implement all recommendations made by the Evaluator within 90 days of the Effective Date of this Agreement. The Registrant and Licensee must petition and receive the approval of the Board to exempt or postpone implementation of any particular recommendation.

(d) Within six months of the Effective Date of this Agreement, the Registrant and Licensee shall provide documentation satisfactory to the Board that the Evaluator, at the expense of the Registrant and Licensee, has conducted a second inspection of Registrant and prepared a written report after an analysis as described in Paragraph (5) above, and further, as to whether the recommendations made by the Evaluator in the First Report have been implemented ("the Second Report").

(e) The Registrant and Licensee will arrange for the Evaluator to provide a copy of the Second Report as described in Paragraph 5(d) directly to the Board within fourteen days of the inspection.

~~(f) The Registrant and Licensee will update Standard Operating Procedures on a biannual~~

basis.

(g) The Registrant and Licensee will keep a written report of each adverse event reported and make such reports available for review by the Board upon request.

6. If the Registrant and Licensee successfully complete the requirements of paragraph 5, its registration and his license will not be placed on probation.
7. If the Registrant and the Licensee fail to successfully complete the requirements of paragraph 5, the Stay will be withdrawn by the Board and the Board's order of Probation for a Period of One (1) Year ("Probation") will be imposed upon the Registrant and Licensee without the necessity of additional proceedings pursuant to G. L. c. 30A. The terms and conditions of Probation will be determined by the Board at that time and may include, but not be limited to practice restrictions, monitoring conditions, appearances before the Board, and continuing education and training.
8. This Agreement and its contents shall be incorporated into the records maintained by the Board. This Agreement and its contents are matters of public record, and are subject to disclosure without limitation to the public and equivalent state licensing boards.
9. The Board agrees that in return for the execution and fulfillment of the requirements of this Agreement by the Registrant and Licensee, the Board will not advance the prosecution of the Registrant and Licensee pursuant to the Complaints; any and all other rights of the Board to take action within the scope of its authority are expressly reserved.
10. The Registrant and Licensee understand and agree that the failure to accept the terms of this Agreement shall nullify the representations contained herein, and permit the Board to initiate formal adjudicatory action under the State Administrative Procedure Act, G.L. c. 30A, and the Standard Adjudicatory Rules of Practice and Procedure, 801 CMR 1.00 *et seq.*
11. The Registrant and Licensee understand and agree that the decision to enter into this Agreement and to accept the terms and conditions herein described is a final act and is not subject to reconsideration or judicial review.
12. The Registrant and Licensee state legal counsel has been consulted in connection with the decision to enter into this Agreement and if not, that there was an opportunity to do so.
13. The Registrant and Licensee certify this document entitled "Consent Agreement" has been read. The Registrant and Licensee understand that, by executing this Agreement, the Registrant and Licensee are waiving any right to a formal hearing with rights to confront and cross-examine witnesses, to call witnesses, to present evidence, to testify on its own behalf, to contest the allegations, to present oral argument, to appeal to court in the event of an adverse ruling, and all other rights set forth in G.L. c. 30A and 801 CMR 1.01 *et seq.*

NEW ENGLAND
COMPOUNDING CENTER

By: Barry J. Cadden
Barry J. Cadden, R.Ph.
Director of Pharmacy

Date: 1/5/06

Barry J. Cadden
Barry J. Cadden R.Ph.
Manager of Record
Date: 1/5/06

BOARD OF REGISTRATION
IN PHARMACY

By: Karen Ryle
Karen Ryle, R.Ph., M.S.
President

Effective Date: 1/10/06

Board Dec. No. 1210, 1211
Cert Mail No.



RESPONDING TO COMMITTEE DOCUMENT REQUESTS

In responding to the document request, please apply the instructions and definitions set forth below:

INSTRUCTIONS

1. In complying with this request, you should produce all responsive documents that are in your possession, custody, or control or otherwise available to you, regardless of whether the documents are possessed directly by you.
2. Documents responsive to the request should not be destroyed, modified, removed, transferred, or otherwise made inaccessible to the Committee.
3. In the event that any entity, organization, or individual named in the request has been, or is currently, known by any other name, the request should be read also to include such other names under that alternative identification.
4. Each document should be produced in a form that may be copied by standard copying machines.
5. When you produce documents, you should identify the paragraph(s) and/or clause(s) in the Committee's request to which the document responds.
6. Documents produced pursuant to this request should be produced in the order in which they appear in your files and should not be rearranged. Any documents that are stapled, clipped, or otherwise fastened together should not be separated. Documents produced in response to this request should be produced together with copies of file labels, dividers, or identifying markers with which they were associated when this request was issued. Indicate the office or division and person from whose files each document was produced.
7. Each folder and box should be numbered, and a description of the contents of each folder and box, including the paragraph(s) and/or clause(s) of the request to which the documents are responsive, should be provided in an accompanying index.
8. Responsive documents must be produced regardless of whether any other person or entity possesses non-identical or identical copies of the same document.
9. The Committee requests electronic documents in addition to paper productions. If any of the requested information is available in machine-readable or electronic form (such as on a computer server, hard drive, CD, DVD, back up tape, or removable computer media such as thumb drives, flash drives, memory cards, and external hard drives), you should immediately consult with Committee staff to determine the appropriate format in which to produce the information. Documents produced in electronic format should be organized, identified, and indexed electronically in a manner comparable to the organizational structure called for in (6) and (7) above.

10. If any document responsive to this request was, but no longer is, in your possession, custody, or control, or has been placed into the possession, custody, or control of any third party and cannot be provided in response to this request, you should identify the document (stating its date, author, subject and recipients) and explain the circumstances under which the document ceased to be in your possession, custody, or control, or was placed in the possession, custody, or control of a third party.

11. If any document responsive to this request was, but no longer is, in your possession, custody or control, state:

- a. how the document was disposed of;
- b. the name, current address, and telephone number of the person who currently has possession, custody or control over the document;
- c. the date of disposition;
- d. the name, current address, and telephone number of each person who authorized said disposition or who had or has knowledge of said disposition.

12. If any document responsive to this request cannot be located, describe with particularity the efforts made to locate the document and the specific reason for its disappearance, destruction or unavailability.

13. If a date or other descriptive detail set forth in this request referring to a document, communication, meeting, or other event is inaccurate, but the actual date or other descriptive detail is known to you or is otherwise apparent from the context of the request, you should produce all documents which would be responsive as if the date or other descriptive detail were correct.

14. The request is continuing in nature and applies to any newly discovered document, regardless of the date of its creation. Any document not produced because it has not been located or discovered by the return date should be produced immediately upon location or discovery subsequent thereto.

15. All documents should be bates-stamped sequentially and produced sequentially. In a cover letter to accompany your response, you should include a total page count for the entire production, including both hard copy and electronic documents.

16. Two sets of the documents should be delivered to the Committee, one set to the majority staff in Room 316 of the Ford House Office Building and one set to the minority staff in Room 564 of the Ford House Office Building. You should consult with Committee majority staff regarding the method of delivery prior to sending any materials.

17. In the event that a responsive document is withheld on any basis, including a claim of privilege, you should provide the following information concerning any such document: (a) the reason the document is not being produced; (b) the type of document; (c) the general subject matter; (d) the date, author and addressee; (e) the relationship of the author and addressee to each

other; and (f) any other description necessary to identify the document and to explain the basis for not producing the document. If a claimed privilege applies to only a portion of any document, that portion only should be withheld and the remainder of the document should be produced. As used herein, "claim of privilege" includes, but is not limited to, any claim that a document either may or must be withheld from production pursuant to any statute, rule, or regulation.

18. If the request cannot be complied with in full, it should be complied with to the extent possible, which should include an explanation of why full compliance is not possible.

19. Upon completion of the document production, you should 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 which reasonably could contain responsive documents; (2) documents responsive to the request have not been destroyed, modified, removed, transferred, or otherwise made inaccessible to the Committee since the date of receiving the Committee's request or in anticipation of receiving the Committee's request, and (3) all documents identified during the search that are responsive have been produced to the Committee, identified in a privilege log provided to the Committee, as described in (17) above, or identified as provided in (10), (11) or (12) above.

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, working papers, records, notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, interoffice and intra-office communications, electronic mail ("e-mail"), instant messages, calendars, contracts, cables, notations of any type of conversation, telephone call, meeting or other communication, bulletins, printed matter, computer printouts, 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, power point presentations, spreadsheets, and work sheets. The term "document" includes all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments to the foregoing, as well as any attachments or appendices thereto. The term "document" also means any graphic or oral records or representations of any kind (including, without limitation, photographs, charts, graphs, voice mails, microfiche, microfilm, videotapes, recordings, and motion pictures), electronic and mechanical records or representations of any kind (including, without limitation, tapes, cassettes, disks, computer server files, computer hard drive files, CDs, DVDs, back up tape, memory sticks, recordings, and removable computer media such as thumb drives, flash drives, memory cards, and external hard drives), 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, electronic format, disk, videotape or otherwise. A document bearing any notation not part of the original text is considered to be a separate document. A draft or non-identical copy is a separate document within the meaning of this term.

2. The term "documents in your possession, custody or control" means (a) documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, or representatives acting on your behalf; (b) documents that you have a legal right to obtain, that you have a right to copy, or to which you have access; and (c) documents that have been placed in the possession, custody, or control of any third party.
3. The term "communication" means each manner or means of disclosure, transmission, or exchange of information, in the form of facts, ideas, opinions, inquiries, or otherwise, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether face-to-face, in a meeting, by telephone, mail, e-mail, instant message, discussion, release, personal delivery, or otherwise.
4. The terms "and" and "or" should be construed broadly and either conjunctively or disjunctively as necessary to bring within the scope of this request any information which might otherwise be construed to be outside its scope. The singular includes the plural number, and vice versa. The masculine includes the feminine and neuter genders.
5. The terms "person" or "persons" mean natural persons, firms, partnerships, associations, limited liability corporations and companies, limited liability partnerships, corporations, subsidiaries, divisions, departments, joint ventures, proprietorships, syndicates, other legal, business or government entities, or any other organization or group of persons, and all subsidiaries, affiliates, divisions, departments, branches, and other units thereof.
6. The terms "referring" or "relating," with respect to any given subject, mean anything that constitutes, contains, embodies, reflects, identifies, states, refers to, deals with, or is in any manner whatsoever pertinent to that subject.
7. The term "Executive Office of the President" means and refers to any of its offices, subdivisions, entities, officials, administrators, employees, attorneys, agents, advisors, consultants, staff, or any other persons acting on behalf or under the control or direction of the Executive Office of the President, including but not limited to the National Economic Council, the Office of Climate Change and Energy Policy, and the Office of Management and Budget.
8. The Term "Office of the Vice President" means and refers to any of its offices subdivisions, entities, officials, administrators, employees, attorneys, agents, advisors, consultants, staff, or any other persons acting on behalf or under the control or direction of the Office of the Vice President.
9. The term "Department of Energy" means and refers to any of its offices, subdivisions, entities, officials, administrators, employees, attorneys, agents, advisors, consultants, staff, or any other persons acting on behalf or under the control or direction of the Department of Energy.

10. The term "Department of Defense" means and refers to any of its offices, subdivisions, entities, officials, administrators, employees, attorneys, agents, advisors, consultants, staff, or any other persons acting on behalf or under the control or direction of the Department of Defense.

11. The term "Solyndra, Inc." means and refers to any of its offices, subdivisions, entities, officials, officers, administrators, employees, attorneys, agents, advisors, consultants, staff, lobbyists, or any other persons acting on behalf or under the control or direction of Solyndra, Inc.

12. The term "investor" means and refers to any individual or entity that invested or committed any money, capital, or anything of value to Solyndra, Inc., including their offices, subdivisions, entities, officials, administrators, employees, attorneys, agents, advisors, consultants, staff, or any other persons acting on behalf or under the control or direction of the investor.

13. The terms "you" or "your" mean and refers to

For government recipients:

"You" or "your" means and refers to you as a natural person and the United States and any of its agencies, offices, subdivisions, entities, officials, administrators, employees, attorneys, agents, advisors, consultants, staff, or any other persons acting on your behalf or under your control or direction; and includes any other person(s) defined in the document request letter.