

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

<b>In Re: Actos (Pioglitazone) Products Liability Litigation</b>	* * * * * *	<b>6:11-md-2299</b>
<b>This Document Applies to:</b>	* * * *	<b>JUDGE DOHERTY</b>  <b>MAGISTRATE JUDGE HANNA</b>

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**DEFENDANT FACT SHEET**

For each Plaintiff from whom a substantially complete and verified Plaintiff Fact Sheet (“PFS”) has been received, Takeda Pharmaceuticals America, Inc.; Takeda Pharmaceuticals U.S.A. Inc. f/k/a Takeda Pharmaceuticals North America, Inc. and Takeda Global Research & Development Center, Inc. (collectively “TAKEDA”); and Eli Lilly and Company (“LILLY” or collectively with TAKEDA as “DEFENDANTS”) must complete this Defendant Fact Sheet (“DFS”) and identify or provide documents and/or data responsive to the questions set forth below to the best of their knowledge. If a named party to the lawsuit, Defendant LILLY must complete a DFS only if the Plaintiff alleges use of Actos<sup>1</sup> beginning on or before December 31, 2007. For cases in which Plaintiff alleges use of Actos® solely between January 1, 2008 and December 31, 2008, Defendant LILLY shall provide the names of the LILLY sales representatives who called on Plaintiff’s prescribing physician(s) and the dates of those calls.

In completing this DFS, you are under oath and must provide information that is true and correct to the best of your knowledge. If you cannot recall all of the details requested, please provide as much information as you can. You must supplement your responses if you learn that they are incomplete or incorrect in any material respect. You must also supplement your responses in the event that additional information is provided from the Plaintiff that relates to the questions raised in the DFS. The DFS shall be completed in accordance with the requirements and guidelines set forth in the applicable Case Management Order.

In the event the DFS does not provide you with enough space for you to complete your responses or answers, please attach additional sheets if necessary. Please identify any documents that you are producing as responsive to a question or request by bates number.

This DFS must be completed and served on each Plaintiff’s counsel identified in the PFS 90 days after the date that a substantially complete and verified Plaintiff Fact Sheet (PFS) has been served on Defendants.

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<sup>1</sup> As used herein, the term “Actos” includes pioglitazone hydrochloride, Actos®, ACTOplus Met®, ACTOplus Met XR®, and Duetact®.

## DEFINITIONS

As used herein, the terms “YOU,” “YOUR,” or “YOURS” means the responding Defendants.

“DEFENDANTS” shall mean and refer to those companies involved in the development, manufacture and distribution of the drugs known as ACTOS, including Takeda Pharmaceuticals America, Inc.; Takeda Pharmaceuticals U.S.A. Inc. f/k/a Takeda Pharmaceuticals North America, Inc.; Takeda Global Research & Development Center, Inc.; Takeda Pharmaceutical Company Limited; Takeda Pharmaceuticals LLC; Takeda Pharmaceuticals International Inc.; and Takeda California, Inc. f/k/a Takeda San Diego Inc. (collectively “TAKEDA”); and Eli Lilly and Company (“LILLY” or collectively with TAKEDA as “DEFENDANTS”).

TAKEDA and LILLY, unless specifically defined to include a third-party, shall each answer each document request and question that not only calls for your knowledge, but also for all knowledge that is available to you by reasonable inquiry, including inquiry of your "officers," "directors," "agents," "employees," and attorneys.

As used herein, the term “DOCUMENTS” and/or “DOCUMENTATION” are coextensive with the meaning of the terms “DOCUMENTS,” “writings,” and “tangible things,” and shall have the broadest possible meaning and interpretation and shall, without limitation, mean and refer to any written, printed, typed, photostatic, photographed, recorded, computer generated, computer-stored, or otherwise maintained record or COMMUNICATION or representation, including (i) any data compilation in any form, whether comprised of letters, words, numbers, pictures, sounds, bytes, emails, electronic signals or impulses, electronic data, active files, deleted files, file fragments, or any combination thereof; (ii) all memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, projections, estimates, working papers, accounts, analytical records, reports and/or summaries of investigations, opinions or reports of consultants, opinions or reports of experts, opinions or reports of accountants, other reports, trade letters, press releases, comparisons, books, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, forecasts, drawings, diagrams, instructions, minutes of meetings or COMMUNICATIONs of any type; (iii) video files, audio files, inter- and intra-office COMMUNICATIONs, questionnaires, surveys, charts, graphs, photographs, phonographs, films, tapes, discs, data cells, drums, printouts and all other compiled data (translated, if necessary, through intermediary or other devices into usable forms); (iv) any records or information maintained on, stored in or generated on any electronic transfer or storage system, any preliminary versions, drafts or revisions of any of the foregoing; (v) and other writings or DOCUMENTS of whatever description or kind, whether prepared by DEFENDANTS or authorized by or on behalf of DEFENDANTS, all non-identical copies and drafts of any of the above-described DOCUMENTS currently or formerly in the possession, custody or control of DEFENDANTS, or the former or present directors, officers, counsel, agents, employees, partners, consultants, principals, and/or persons acting on DEFENDANTS’ behalf.

As used herein, the word “COMMUNICATION” and/or “CORRESPONDENCE” shall mean and refer to any oral, written, spoken, or electronic transmission of information, including, but not limited to, meetings, discussions, conversations, telephone calls, memoranda, letters, emails,

text messages, postings, instructions, conferences, seminars, or any other exchange of information between DEFENDANTS and any other person or entity.

As used herein, the term “RELATING TO,” “RELATE TO,” “REFERRING TO,” “REFER TO,” “REFLECTING,” “REFLECT,” “CONCERNING,” or “CONCERN” shall mean and refer to any DOCUMENT or COMMUNICATION evidencing, regarding, concerning, discussing, embodying, describing, summarizing, containing, constituting, showing, mentioning, reflecting, pertaining to, dealing with, relating to, referring to in any way or manner, or in any way logically or factually, connecting with the matter described in that paragraph of these demands, including DOCUMENTS or COMMUNICATIONS attached to or used in the preparation of or concerning the preparation of the DOCUMENTS or COMMUNICATIONS.

As used herein, “ELECTRONIC DATA” or “DATA” shall mean and refer to the original (native electronic format), and any non-identical copies (whether non-identical because of notes made on copies or attached comments, annotations, marks, transmission notations, or highlighting of any kind) of writings of every kind and description whether inscribed by mechanical, facsimile, electronic, magnetic, digital, or other means. Electronic data includes, by way of example only, computer programs (whether private, commercial, or works-in-progress), programming notes or instructions, activity listings of electronic mail receipts and/or transmittals, output resulting from the use of any software program, including word processing DOCUMENTS, spreadsheets, database files, charts, graphs and outlines, electronic mail, operating systems, source code of all types, peripheral drivers, PIF files, batch files, ASCII files, and any and all miscellaneous files and/or file fragments, regardless of the media on which they reside and regardless of whether said electronic data consists of an active file, deleted file or file fragment. Electronic data includes any and all items stored on computer memories, hard disks, floppy disks, CD-ROMs, removable media such as zip drives, USB drives, storage cartridges, Bernoulli Boxes and their equivalent, magnetic tapes of all types, microfiche, punched cards, punched tape, computer chips, including, but not limited to, EPROM, PROM, RAM and ROM, on or in any other vehicle for digital data storage and/or transmittal. The term electronic data also includes the file, folder tabs and/or containers and labels appended to, or associated with, any physical storage device associated with each original and/or copy.

As used herein, “ELECTRONIC MEDIA” shall mean and refer to any magnetic or other storage media device used to record electronic data. Electronic media devices may include computer memories, hard disks, floppy disks, CDROM, removable media such as Bernoulli Boxes and their equivalent, magnetic tapes of all types, microfiche, punched cards, punched tape, computer chips, including, but not limited to, EPROM, PROM, RAM and ROM, or on or in any other vehicle for digital data storage and/or transmittal.

As used herein, “KEY OPINION LEADER” or “THOUGHT LEADER” shall mean and refer to physicians, often academic researchers, who are believed by DEFENDANTS to be effective at transmitting messages to their peers and others in the medical community. This term shall mean and refer to any doctors or medical professionals hired by, consulted with, or retained by DEFENDANTS to, amongst other things, consult, give lectures, respond to media inquires, conduct clinical trials, write articles or abstracts, sign their names as authors to articles or

abstracts written by others, and occasionally make presentations on their behalf at regulatory meetings or hearings.

As used herein, the phrase “PROVIDED” means sold, given, distributed, shipped, delivered or otherwise placed into the stream of commerce.

As used herein, the phrase “TREATING HEALTH CARE PROVIDER” means any physician, medical provider, practice, clinic, person, or entity identified with particularity in the PFS who prescribed and/or dispensed Actos® to the Plaintiff and up to two (2) additional health care providers who have treated the Plaintiff for their alleged Actos®-related injuries and have been designated by the Plaintiff pursuant to the provisions of Case Management Order: Defendant Fact Sheets. Treating Health Care Provider” shall refer not only to the medical professional who prescribed Actos® to the Plaintiff or up to two additional health care providers who have treated the Plaintiff for injuries claimed to be related to Actos®, but also anyone working within his or her office, including, but not limited to, employees, nurses, nurse practitioners, and office or clerical staff of the clinic, practice, or medical group.

As used herein, the phrase “PROMOTIONAL ITEMS” means any and all promotion items, marketing devices, freebies, merchandise, handouts, meals, or any other items related to Actos®, including, but not limited to, physical items marked with the Actos® trademark such as anatomical models, notepads, post-it-notes, pens, flashlights, office supplies, models for patient demonstration, diagnostic tools and aids, medical assessment and dosage calculators, pharmacy and pharmacist tools, patient compliance tools, custom medical calculators and software, branded apparel, leather portfolios, prescription pads, picture frames, letter openers, clipboards, water bottles, coffee mugs/cups, pocket/pen lights, key chains, badge-holders, bags, travel accessories, and other “freebies” provided to Prescribing Health Care Providers.

**I. Case Information**

This DFS pertains to the following case:

Case caption: \_\_\_\_\_

Civil Action No. \_\_\_\_\_

Court in which action was originally filed: \_\_\_\_\_

Date that this DFS was completed: \_\_\_\_\_

Name and Address of all persons who provided information responsive to the questions posed in this DFS:

A: \_\_\_\_\_  
(Name)

\_\_\_\_\_  
(Job Title)

\_\_\_\_\_  
(Address)

\_\_\_\_\_  
(Phone Number)

B: ✓

\_\_\_\_\_  
(Name)

\_\_\_\_\_  
(Job Title)

\_\_\_\_\_  
(Address)

\_\_\_\_\_  
(Phone Number)

## II. Contacts With Treating Health Care Providers

For each Treating Health Care Provider identified in the PFS, please state the following:

### A. Dear Doctor Letters:

1. Please identify and any "Dear Doctor," "Dear Health Care Provider," "Dear Colleague," or any other similar type of document or letter sent to the Plaintiff's Treating Health Care Provider concerning Actos®. Please identify each such document or letter by stating the name and address of the person(s) who sent the document or letter; the date that each document or letter was sent; the name and address of the person(s) to whom each document or letter was sent; and identify by Bates number any and all documentation, including lists or database records, which demonstrates that these documents or letters were sent.

Sender (Name and Address)	Letter or Document Date	Recipient (Name and Address)	Bates Number of Supporting Documentation

2. Please identify the person(s) and/or data sources in which the information

provided in Section II. A. was retrieved.

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B. Physician's Information Request Letters ("PIR"):

1. Please indicate if any of the Treating Health Care Provider(s) identified in the PFS has ever initiated a PIR by identifying the name and address of the sender of the PIR; the date it was sent; the name and address of the recipient; and whether or not a response to the PIR or similar document was sent.

Sender (Name and Address)	PIR Date	Recipient (Name and Address)	Response Sent? (Yes or No)

2. For each PIR in which a response was sent as indicated by a "Yes" above, please identify the format of the response; the date the response was sent; the name and address of the sender of the response; the name and address of the recipient of the response; and provide or identify by Bates number any and all documentation, including lists or database records, which demonstrates that these responsive documents were sent.

Original PIR or Request Document Date	Format of Response (Letter or Otherwise)	Date Response Sent	Response Sender (Name and Address)	Response Recipient (Name and Address)	Bates Number of Supporting Documentation

3. Please identify the person(s) and/or data sources in which the information provided in Section II. B. was retrieved.

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C. Other Contacts

- For each Treating Health Care Provider identified in the PFS, please identify by name any of the Defendants' Sales Representatives and/or any other detail person ("Representative") who came in contact with the Treating Health Care Provider and provide dates of each contact that relate to Actos®. Please indicate the Representative's dates of employment with the Defendant, and, if that Representative is no longer employed by the Defendant, provide the last known address and phone number of that Representative.

Treating Health Care Provider	Name of Representative (Provide Last Known Address and Telephone Number if No Longer Employed)	Dates of Employment	Date(s) of Contact

- For each Representative identified in Section II.C.1., please indicate the designated Territory in which the Representative was assigned and the Representative's applicable Supervising District Manager(s) and Regional Sales Director(s).

Representative	Territory	Supervising District Manager(s)	Regional Sales Director(s)

- Have Defendants or their representatives ever provided any of Plaintiff's Treating

Health Care Providers with Actos® samples?

Yes \_\_\_\_\_ No \_\_\_\_\_

- A. If the answer is “yes,” please state the Treating Health Care Provider that received the samples; the dates in which such samples were provided; the amount, dosage, and lot numbers of such samples; and the name of the Representative who provided the samples.

HealthCare Provider	Date Shipped to and/or Provided	Amount, Dosage, and Lot Numbers	Representative who Provided

4. For each Treating Health Care Provider, please state whether Defendants or their representatives ever provided him/her with “Promotional Items.”

Yes \_\_\_\_\_ No \_\_\_\_\_

- A. If the answer is “yes,” please state the Treating Health Care Provider that received the Promotional Items; the name of the Representative who provided the items; the dates in which such items were provided; a description and quantity of the items.

Healthcare Provider	Representative who Provided	Date(s) Provided	Description and Quantity

*To the extent available, a physical sample of the promotional item shall be provided to plaintiff's counsel.*

5. For each Representative identified in Section II.C.1., please identify or produce all call notes for calls with Plaintiff's Treating Health Care Provider(s).

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7. For each Representative identified in Section II.C.1., please identify or produce all informational or promotional information that the Representative distributed to any of Plaintiff's Prescribing Health Care Providers.

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8. Please identify the person(s) and/or data sources in which the information provided in Section II. C. was retrieved.

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**III. Consulting With Plaintiff's Treating Health Care Provider**

**A. Consulting and Professional Relationships**

1. If any of Plaintiff's Treating Health Care Providers identified in the PFS have been retained or compensated as a "key opinion leader," "thought leader," member of a "speaker's bureau," "clinical investigator," "consultant," or in any other capacity relating to the subject of diabetes medications (including Actos®) and/or the treatment of diabetes, bladder cancer, congestive heart failure, or myocardial infarction please identify date(s) that the Treating Health Care Provider was consulted, retained or compensated; the nature of the affiliation; and the amount of remuneration for expenses and/or fees.

Treating Health Care Provider	Date(s) that Treating Health Care Provider was Consulted, Retained or Compensated	Nature of Affiliation	Remuneration


2. For any Treating Health Care Provider identified in response to III.A.1., please identify or produce all documents or correspondence provided to the Treating Health Care Provider by Takeda or Eli Lilly concerning the potential benefits and/or risks of diabetes medications (including Actos®) and/or the treatment of diabetes, bladder cancer, congestive heart failure, or myocardial infarction.

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3. For each Treating Health Care Provider identified in Section III.A.1., please identify or produce any documentation relating to monetary compensation paid to that Treating Health Care Provider, including, but not limited to, completed 1099 forms or other IRS documentation.

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4. For each Treating Health Care Provider identified in Section III.A.1., please identify or produce all documents relating to all consulting agreements contracts, and retainer agreements entered into with the Treating Health Care Provider.

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5. For each Treating Health Care Providers identified in Section III.A.1., please indicate whether they were ever attended any Defendant- sponsored conferences or events (“Programs”) relevant to the treatment of diabetes, bladder cancer, congestive heart failure, or myocardial infarction, and provide the title, location,

date(s) and topic(s) of the program.

Treating Health Care Provider	Title, Location, and Date(s) of Program	Topic(s) of Program

6. For any Program identified in response to III.A.5., please identify all speakers at the Program.

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**IV. Plaintiff's Treating Health Care Provider's Practices**

For each Treating Health Care Provider identified in the PFS, please state and produce the following:

- A. Do you have or have you had access to any database or other information that tracks the prescribing or treating practices of Plaintiff's Treating Health Care Provider(s) with respect to Actos® or any other diabetes drug (including, but not limited to, the product(s) prescribed, the number of prescriptions, the number of refills, and the time when these products were prescribed or refilled).

Yes \_\_\_\_\_ No \_\_\_\_\_

If your answer is "yes", please identify the database or document which captures that information, to the extent available:

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- B.. Please identify the person(s) and/or data sources in which the information provided in Section IV. was retrieved.

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V. **Plaintiff's Medical Condition**

- A. Have you been contacted by Plaintiff, any of his/her Treating Health Care Providers, or anyone acting on behalf of Plaintiff (other than Plaintiff's counsel) concerning Plaintiff?

Yes \_\_\_\_\_ No \_\_\_\_\_

- B. If you have been contacted by any person or entity concerning the Plaintiff, please state the name of the person(s) who contacted you and the name and address of the person(s) who contacted in response.

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- C. Please identify or produce all documents which reflect any communication between any person and you concerning Plaintiff.

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- D. Please identify or produce any and all documents, data, information, notes and/or materials produced in the course of your response, evaluation, investigation, and/or follow up after the submission of any MedWatch form and/or Adverse Event Report on behalf of or in reference to the Plaintiff, including back-up documentation and any evaluation or investigation you conducted. With respect to adverse event reports generated by the receipt of a legal claim or complaint, Defendants shall produce the adverse event data, but not the underlying legal claim or complaint, or any other related document(s) generated or obtained through the legal process (e.g. medical records, discovery responses, legal correspondence, etc.)

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- E. Please identify the person(s) and/or data sources in which the information provided in Section V. was retrieved.

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**VI. Advertising**

- A. Aside from national advertising (i.e. advertising that was not directed to any specific geographic region), did you advertise Actos® in the Media Market in which Plaintiff lived at the time that he or she used Actos® as disclosed in the PFS?

Yes \_\_\_\_\_ No \_\_\_\_\_

1. If your answer to VI.A. is “yes,” please provide, to the extent available, the name, identity, and/or title of the advertisement; the nature of the media (i.e., print or television); the media location(s), outlet(s), publication(s) and/or channel(s); and the date(s) the advertisement ran.

Name/Identity/Description of the Advertisement	Nature of Media (print or television)	Media Location(s), Outlet(s), Publication(s) and/or Channels	Dates that Advertisements Ran

- B. Aside from national advertising (i.e. advertising that was not directed to any specific geographic region), did you advertise Actos® in the Media Market in which Plaintiff’s Treating Health Care Provider’s office was located, as listed in the PFS, at the time that Plaintiff used Actos® as disclosed in the PFS?

Yes \_\_\_\_\_ No \_\_\_\_\_

1. If your answer to VI.B. is “yes,” please provide, to the extent available, the name, identity, and/or title of the advertisement; the nature of the media (i.e., print or television); the media location(s), outlet(s), publication(s) and/or channel(s); and the date(s) the advertisement ran.

Name/Identity/Description of the Advertisement	Nature of Media (print or television)	Media Location(s), Outlet(s), Publication(s) and/or Channels	Dates that Advertisements Ran

**VII. Documents**

- A. To the extent you have not already done so, please produce a copy of all documents and things that fall into the categories listed below. These include documents in the possession of any of your present and former employees, including information provided to your attorneys:
1. Any document which relates to or refers to Plaintiff.
  2. Any document sent to or received from any of Plaintiff’s Treating Health Care Providers.
  3. “Dear Doctor,” “Dear Health Care Provider,” “Dear Colleague” letters, or PIR’s sent to or received from Treating Health Care Providers and any and all other related documentation.
  4. Any and all documentation sent to or received during the course of communications with Plaintiff’s Treating Health Care Providers and Defendants’ Sales Representatives, and/or any other detail representatives.
  5. Promotional items and/or any other tangible items exchanged between Plaintiff’s Treating Health Care Providers and Defendants’ Sales Representatives, Marketing Organization Representatives, Employees, and/or any other detail representatives.
  6. The call notes for calls with Plaintiff’s Treating Health Care Provider(s), for each Sales Representatives, and/or any other detail representatives identified in Sections I-VI above.
  7. Any and all documentation relating to your retention and/or compensation of any of Plaintiff’s Treating Health Care Providers as a “key opinion leader,” “thought leader,” member of a “speaker’s bureau,” “clinical investigator,” “consultant,” or in any other capacity relating to the subject of diabetes medications (including Actos®).

8. Any and all documents including tax returns for any amounts of money paid to Plaintiff's Treating Health Care Providers.
9. Any and all documents relating to Plaintiff's Treating Health Care Provider(s)' attendance at Defendant sponsored conferences or events relevant to the treatment of diabetes, bladder cancer, congestive heart failure, or myocardial infarction, including, but not limited to, programs, brochures, agendas, attendee lists, speaker lists, and/or promotional materials.
10. Any and all documents reflecting any actual communication between you and Plaintiff's Treating Health Care Providers concerning the risks of the injuries of Actos®.
11. Any and all documents reflecting any contracts or actual communications between you and any of Plaintiff's Treating Health Care Providers regarding Actos®.
12. Any market surveys or other surveys to or received from any of Plaintiff's Treating Health Care Providers.
13. Any and all documentation which purports to describe, analyze, investigate, track, and/or report the prescribing practices of any of Plaintiff's Treating Health Care Providers relating to Actos®, subject to the approval and/or agreement of the owner (IMS Health) of the prescribing data to release the data, which approval and/or agreement Defendant will request.
14. Any and all documentation relating to contact between you and the Plaintiff (other than with Plaintiff's counsel).
15. Any and all documents, data, information, notes and/or materials produced in the course of your response, evaluation, investigation, and/or follow up after the submission of any MedWatch form and/or Adverse Event Report on behalf of or in reference to the Plaintiff, including back-up documentation and any evaluation or investigation you conducted. With respect to adverse event reports generated by the receipt of a legal claim or complaint, Defendants shall produce the adverse event data, but not the underlying legal claim or complaint, or any other related document(s) generated or obtained through the legal process (e.g. medical records, discovery responses, legal correspondence, etc.)
16. Aside from national advertising, copies of any and all advertisements directed toward the media markets in which the Plaintiff resided and/or Plaintiff's Treating Health Care Provider's office is located.

17. Any other document, printout, communication or tangible item identified in, referred to, and/or pertaining to any of the requests or responses in Sections I-VII above.

**Certification of Counsel**

Undersigned counsel for Defendants Takeda Pharmaceuticals U.S.A., Inc., Takeda Pharmaceuticals America, Inc., and Takeda Global Research & Development Center, Inc. (Counsel) certifies that Counsel and/or members or associates in Counsel's firm instructed Counsel's Firm, Defendants, Defendants' other current or former attorneys (Other Attorneys) and/or agents for any of the foregoing, to engage in best efforts to identify, locate and supply all responsive documents demanded in the Request to Produce to Defendants approved by Case Management Order \_\_ that were in the possession, custody or control of Counsel, Defendants, Other Attorneys and/or agents, and Counsel further certifies that Counsel has a good faith belief that these instructions were followed by all of the aforementioned persons.

Date: \_\_\_\_\_

Signature: \_\_\_\_\_

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Print Name

\_\_\_\_\_  
Date