

1 this Court, including, but not limited to, the Order governing the Production of
2 Electronically Stored Information (Doc. No. 187) (“ESI Order”), the CMO Governing
3 Limitations on Written Discovery, when entered, or this Court’s Local Rules.

4 2. NNI objects to the voluminous nature of these interrogatories paired with the
5 additional sets of interrogatories propounded on NNI, the total number of which exceeds
6 that which is allowed under the Federal Rules of Civil Procedure. Nevertheless, following
7 agreement by the parties, NNI agreed to respond to these interrogatories while reserving
8 its rights to include substantive objections about which the parties will be prepared to
9 meet and confer.

10 3. NNI objects to these interrogatories to the extent they seek information protected
11 by the attorney-client, work-product, or any other applicable privilege or immunity from
12 discovery. Any disclosure of information protected by any such privilege or other
13 immunity shall be deemed inadvertent and shall not constitute a waiver of such privilege
14 or other immunity.

15 4. NNI objects to these interrogatories, including subparts, to the extent they call
16 for information that is not in the possession, custody, or control of NNI, or is a matter of
17 public record or otherwise as accessible to Plaintiffs as to NNI.

18 5. NNI objects to Plaintiffs’ Definitions to the extent such definitions, as
19 incorporated into these interrogatories, renders an interrogatory vague, ambiguous, overly
20 broad, unduly burdensome, and not reasonably calculated to lead to the discovery of
21 admissible evidence. Specifically, NNI objects to Plaintiffs’ definitions of “YOU,”
22 “YOUR,” “YOURS,” or “Defendants” as vague and ambiguous. NNI’s responses to
23 interrogatories herein construe terms “You,” “Your,” or “Defendant” to mean Novo
24 Nordisk Inc. only.

25 6. NNI objects to these interrogatories to the extent they seek information from
26 time periods that are irrelevant or inapplicable to Victoza®.

27 7. NNI objects to these interrogatories to the extent they seek information
28 concerning products other than Victoza® (liraglutide).

1 8. NNI objects to these interrogatories to the extent they seek to function as
2 document requests.

3 9. NNI objects to these interrogatories to the extent they call for the identification
4 of all documents, individuals, information, or communication as well as any and/or every
5 document, individual, piece of information, or communication when all relevant facts can
6 be obtained from fewer than “all” documents or “any” document.

7 10. NNI objects to these interrogatories to the extent they seek information
8 pertaining to injuries, alleged side effects, or adverse reactions not at issue in this
9 Litigation on the grounds that such interrogatories are not relevant, overly broad, and not
10 reasonably calculated to lead to the discovery of admissible evidence.

11 11. NNI objects to these interrogatories to the extent they seek information related
12 to foreign regulatory submissions, requirements, or activities, or the direction of foreign
13 regulatory bodies, because it is neither relevant nor reasonably calculated to lead to the
14 discovery of admissible evidence and is unduly burdensome. Such information is subject
15 to different regulatory and legal standards and requirements, and can be influenced by
16 political, cultural, and social differences, including, but not limited to, differences in the
17 practice of medicine.

18 12. NNI objects to these interrogatories to the extent they seek sales, marketing, or
19 advertising information outside of the United States because it is neither relevant nor
20 reasonably calculated to lead to the discovery of admissible evidence and is unduly
21 burdensome to produce in this litigation.

22 13. NNI objects to these interrogatories to the extent the information sought is
23 already in Plaintiffs’ possession, custody or control, or are equally available to the
24 Plaintiffs, on the grounds that such discovery requests are unreasonably cumulative and
25 duplicative, and that the information may be obtained from a source that is more
26 convenient, less burdensome, and less expensive.

27 14. NNI objects to these interrogatories to the extent they seek an analysis or
28 summary of documents or information that is generally available to all parties. NNI

1 objects further pursuant to Federal Rule of Civil Procedure 33(d) on the grounds that the
2 burden of ascertaining such information is substantially the same for Plaintiffs as for
3 NNI.

4 15. NNI objects to these interrogatories to the extent they seek confidential,
5 proprietary, competitively sensitive, or trade secret information. To the extent NNI
6 produces responsive and non-privileged information, any such information will be
7 produced in accordance with the agreed-upon and Court-ordered Protective Order entered
8 in this Litigation.

9 16. NNI objects to these interrogatories to the extent that they are duplicative of the
10 deposition notices for testimony pursuant to Rule 30(b)(6) of the Federal Rules of Civil
11 Procedure that Plaintiffs have also served on NNI in this action.

12 17. NNI objects to these interrogatories to the extent they request NNI to disclose
13 the identity of any individual who allegedly experienced an adverse effect or who
14 reported such an adverse experience on the ground that such a disclosure would violate
15 the patients' or reporters' right to confidentiality under federal law.

16 18. NNI's investigation into this matter is ongoing. Therefore, NNI may be unable
17 to provide full and complete responses to certain interrogatories. NNI will respond to
18 these interrogatories as fully and completely as possible. NNI may supplement these
19 responses as additional, responsive, relevant and non-privileged information becomes
20 available.

21 19. By responding to these interrogatories, NNI does not concede the relevance,
22 materiality, or admissibility of any of the documents sought herein for use as evidence in
23 any hearing or trial. NNI's responses are made subject to, and without waiving, any
24 objections as to relevance, materiality, or admissibility. NNI expressly reserves the right
25 to object to further discovery on the subject matter of any of these requests.

26 20. The applicable foregoing General Objections are incorporated into each of the
27 specific objections and responses that follow. Stating a specific objection or response
28 shall not be construed as a waiver of NNI's general or specific objections.

1 **Reason Why the General Objections Should be Disregarded:**

2 General objections are improper. Plaintiffs cannot know whether information is
3 being limited or completely withheld on the basis of these objections.
4

5 **Basis for their Inclusion:**
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9 **PLAINTIFFS' FIRST SET OF INTERROGATORIES**

10 **INTERROGATORY NO. 1:**

11 Has any employee, officer, director, agent, contractor, director, key opinion leader,
12 member of speaker bureau, advisory board member, or scientific advisor of YOURS
13 corresponded with or supplied information or data to any scientific journal on any of the
14 following topics: incretin mimetic therapies, glucagon-like peptide 1 therapies, dipeptidyl
15 peptidase-4 inhibitor therapies, exenatide, liraglutide, sitagliptin, saxagliptin, alogliptin,
16 and linagliptin? If so, for each, please state:

- 17 a. Correspondent's name, title, address, phone number;
18 b. Journal name(s);
19 c. Date of correspondence; and
20 d. Location of correspondence.

21 **Response to Interrogatory No. 1:**

22 NNI incorporates, as if fully set forth herein, the General Objections by reference.
23 NNI further objects to this interrogatory as vague and ambiguous as it fails to define
24 certain terms and phrases, including "key opinion leader," "member of speaker bureau,"
25 "advisory board member," "scientific advisor," and "corresponded with or supplied
26 information or data." Additionally, NNI objects to this interrogatory to the extent it seeks
27 information concerning non-NNI personnel. NNI further objects to this interrogatory to
28 the extent it seeks information regarding medications other than Victoza®. NNI further

1 objects to this interrogatory to the extent it seeks information unrelated to the alleged
2 risks and injuries at issue in this litigation. NNI further objects to this interrogatory to the
3 extent it seeks information concerning activities outside the United States.

4 Subject to and without waiving its objections, including the General Objections
5 stated above, and pursuant to the parties' agreement on February 3, 2014, NNI will
6 answer this interrogatory more fully at a later time, as needed, once its discovery and
7 document production are more substantially completed and upon mutual agreement by
8 the parties regarding, among other things, the appropriate scope and context of this
9 request.

10
11 **Reason Why the Answer Should be Provided:**

12 Plaintiffs are entitled to know how and to what extent Defendants are influencing
13 or attempting to influence the scientific literature on incretins, and to obtain identifying
14 information for documents and potential witnesses. The relevant issues for general
15 causation are the same here and abroad. Foreign discovery on matters of global scope
16 and importance is proper.

17
18 **Basis for Nondisclosure:**

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21 **INTERROGATORY NO. 2:**

22 Has any employee, officer, director, agent, contractor, director, key opinion leader,
23 member of speaker bureau, advisory board member, or scientific advisor of YOURS
24 submitted a manuscript, case report, article described as an "advertisement," opinion
25 piece or topic to any scientific journal on any of the following topics: incretin mimetic
26 therapies, glucagon-like peptide 1 therapies, dipeptidyl peptidase-4 inhibitor therapies,
27 exenatide, liraglutide, sitagliptin, saxagliptin, alogliptin, and linagliptin? If so, for each,
28 please state:

- 1 a. Individual's name, title, address, phone number who submitted the
2 manuscript, case report, article, opinion piece or topic;
3 b. Journal name(s) to which the manuscript, case report, article, opinion
4 piece or topic was submitted;
5 c. Working title of manuscript, case report, article, opinion piece or topic;
6 d. Date of submission;
7 e. Location of the manuscript, case report, article, opinion piece or topic;
8 f. The amount paid for every manuscript, case report, article, opinion piece
9 or topic for which payment was made by or on behalf of YOU for the
10 publication of such document.

11 **Response to Interrogatory No. 2:**

12 NNI incorporates, as if fully set forth herein, the General Objections by reference.
13 NNI further objects to this interrogatory as vague and ambiguous as it fails to define
14 certain terms and phrases, including "key opinion leader," "member of speaker bureau,"
15 "advisory board member," "scientific advisor," and "advertisement," opinion piece or
16 topic." NNI further objects to this interrogatory to the extent it seeks information
17 concerning non-NNI personnel. NNI further objects to this interrogatory to the extent it
18 seeks information regarding medications other than Victoza®. NNI further objects to this
19 interrogatory to the extent it seeks information unrelated to the alleged risks and injuries
20 at issue in this litigation. NNI further objects to this interrogatory to the extent it seeks
21 information concerning activities outside the United States.

22 Subject to and without waiving its objections, including the General Objections
23 stated above, and pursuant to the parties' agreement on February 3, 2014, NNI will
24 answer this interrogatory more fully at a later time, as needed, once its discovery and
25 document production are more substantially completed and upon mutual agreement by
26 the parties regarding, among other things, the appropriate scope and context of this
27 request.
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3 **Reason Why the Answer Should be Provided:**

4 Plaintiffs are entitled to know how and to what extent Defendants are influencing
5 or attempting to influence the scientific literature on incretins, and to obtain identifying
6 information for documents and potential witnesses. The relevant issues for general
7 causation are the same here and abroad. Foreign discovery on matters of global scope
8 and importance is proper.
9

10 **Basis for Nondisclosure:**
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13 **INTERROGATORY NO. 3:**

14 Has any employee, officer, director, agent, contractor, director, key opinion leader,
15 member of speaker bureau, advisory board member, or scientific advisor of YOURS
16 participated in or supplied information to any expert meeting, panel or committee
17 anywhere in the world, investigating or reviewing glucagon-like peptide 1 based or
18 dipeptidyl peptidase-4 inhibitor therapies? If so, for each, please state:

- 19 a. Individual's name, title, address, phone number who participated in or
20 supplied such information;
21 b. Name and place of meeting, panel or committee the individual
22 participated or supplied information;
23 c. Date(s) of meeting, panel or committee proceedings; and
24 d. Location of all writings, data, correspondence and attachments supplied,
25 received or created through such meeting, panel or committee.

26 **Response to Interrogatory No. 3:**

27 NNI incorporates, as if fully set forth herein, the General Objections by reference.
28 NNI further objects to this interrogatory as vague and ambiguous in that it fails to define

1 certain terms and phrases, including “key opinion leader,” “member of speaker bureau,”
2 “advisory board member,” and “scientific advisor,” and “expert meeting, panel, or
3 committee.” NNI further objects to this interrogatory as overbroad and vague to the
4 extent it seeks information regarding the terms and phrases “any expert meeting, panel or
5 committee” and “anywhere in the world.” NNI further objects to this interrogatory to the
6 extent it seeks information concerning non-NNI personnel. NNI further objects to this
7 interrogatory to the extent it seeks information regarding medications other than
8 Victoza®. NNI further objects to this interrogatory to the extent it seeks information
9 unrelated to the alleged risks and injuries at issue in this litigation. NNI further objects to
10 this interrogatory to the extent it seeks information concerning activities outside the
11 United States.

12 Subject to and without waiving its objections, including the General Objections
13 stated above, and pursuant to the parties’ agreement on February 3, 2014, NNI will
14 answer this interrogatory more fully at a later time, as needed, once its discovery and
15 document production are more substantially completed and upon mutual agreement by
16 the parties regarding, among other things, the appropriate scope and context of this
17 request.

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19 **Reason Why the Answer Should be Provided:**

20 Plaintiffs are entitled to know how and to what extent Defendants are influencing
21 or attempting to influence the scientific community on incretins, and to obtain identifying
22 information for documents and potential witnesses. The relevant issues for general
23 causation are the same here and abroad. Foreign discovery on matters of global scope
24 and importance is proper.

25
26 **Basis for Nondisclosure:**

1 **INTERROGATORY NO. 4:**

2 Has any employee, officer, director, agent, contractor, director, key opinion leader,
3 member of speaker bureau, advisory board member, or scientific advisor of YOURS
4 corresponded with or supplied information or data to the European Medicines Agency
5 (“EMA”) about or in connection with its 2013 “Assessment report for GLP-1 based
6 therapies.” If so, for each, please state:

- 7 a. Correspondent’s name, title, address, phone number;
8 b. Journal name(s);
9 c. Date of correspondence; and
10 d. Location of correspondence.

11 **Response to Interrogatory No. 4:**

12 NNI incorporates, as if fully set forth herein, the General Objections by reference.
13 NNI further objects to this interrogatory as vague and ambiguous as it fails to define
14 certain terms and phrases, including “key opinion leader,” “member of speaker bureau,”
15 “advisory board member,” and “scientific advisor,” and “corresponded with or supplied
16 information or data.” NNI further objects to this interrogatory to the extent it seeks
17 information concerning non-NNI personnel. NNI further objects to this interrogatory to
18 the extent it seeks information regarding medications other than Victoza®. NNI further
19 objects to this interrogatory to the extent it seeks information unrelated to the alleged
20 risks and injuries at issue in this litigation. NNI further objects to this interrogatory to the
21 extent it seeks information concerning the regulatory submissions, requirements,
22 activities, or the direction of the EMA, a foreign regulatory authority, as neither relevant
23 nor reasonably calculated to lead to the discovery of admissible evidence and is unduly
24 burdensome.

25
26 **Reason Why the Answer Should be Provided:**

27 Plaintiffs are entitled to know how and to what extent Defendants are influencing
28 or attempting to influence the scientific community on incretins, and to obtain identifying

1 information for documents and potential witnesses. Defendants cannot use EMA
2 evidence as a “sword” on the one hand, while raising a “shield” to protect that
3 information from inspection and analysis on the other. The relevant issues for general
4 causation are the same here and abroad. Foreign discovery on matters of global scope
5 and importance is proper.
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8 **Basis for Nondisclosure:**
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11 **INTERROGATORY NO. 5:**

12 Has any employee, officer, director, agent, contractor, director, key opinion leader,
13 member of speaker bureau, advisory board member, or scientific advisor of YOURS
14 corresponded with or supplied information or data to any scientific journal about any of
15 the following individuals: Dr. Peter C. Butler, Dr. Michael Elashoff, Dr. Robert Elashoff,
16 Dr. Alexandra E. Butler, Dr. Belinda Gier, Dr. Aleksey V. Matveyenko, Dr. Edwin Gale,
17 Dr. Sonal Singh? If so, for each, please state:

- 18 a. Correspondent’s name, title, address, phone number;
19 b. Journal name(s);
20 c. Date of correspondence; and
21 d. Whereabouts of correspondence .

22 **Response to Interrogatory No. 5:**

23 NNI incorporates, as if fully set forth herein, the General Objections by reference.
24 NNI further objects to this interrogatory as unduly vague and ambiguous as it fails to
25 define certain terms and phrases, including “corresponded with or supplied information
26 or data,” “key opinion leader,” “member of speaker bureau,” “advisory board member,”
27 and “scientific advisor.” NNI further objects to this interrogatory to the extent it seeks
28 information concerning non-NNI personnel. NNI further objects to this interrogatory to

1 the extent it seeks information regarding medications other than Victoza®. NNI further
2 objects to this interrogatory to the extent it seeks information unrelated to the alleged
3 risks and injuries at issue in this litigation. NNI further objects to this interrogatory to the
4 extent it seeks information concerning activities outside the United States.

5 Subject to and without waiving its objections, including the General Objections
6 stated above, and pursuant to the parties' agreement on February 3, 2014, NNI will
7 answer this interrogatory more fully at a later time, as needed, once its discovery and
8 document production are more substantially completed and upon mutual agreement by
9 the parties regarding, among other things, the appropriate scope and context of this
10 request.

11
12 **Reason Why the Answer Should be Provided:**

13 Plaintiffs are entitled to know how and to what extent Defendants are influencing
14 or attempting to influence the scientific community on incretins (the people referred to
15 are incretin scientists and writers), and to obtain identifying information for documents
16 and potential witnesses. The relevant issues for general causation are the same here and
17 abroad. Foreign discovery on matters of global scope and importance is proper.

18
19 **Basis for Nondisclosure:**

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23 **PLAINTIFFS' SECOND SET OF INTERROGATORIES**

24 **General Objections:**

25 (NNI included the same General Objections as those identified above for the First
26 Set of Interrogatories.)
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1 **Reason Why the General Objections Should be Disregarded:**

2 General objections are improper. Plaintiffs cannot know whether information is
3 being limited or completely withheld on the basis of these objections.
4

5 **Basis for their Inclusion:**

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8 **INTERROGATORY NO. 1:**

9 Please identify the name(s) of the company(ies) or other entities that manufactured,
10 marketed, tested, created, distributed, packaged, promoted, and/or sold VICTOZA during
11 each year that VICTOZA was manufactured, marketed, tested, created, distributed,
12 packaged, promoted, and/or sold. If separate companies or other entities were responsible
13 for different aspects of the manufacturing, marketing, testing, creating, distributing,
14 packaging, promoting, and/or selling of VICTOZA, then indicate which company or
15 other entity was responsible for each of the above aspects for each year VICTOZA was
16 manufactured, marketed, tested, created, distributed, packaged, promoted, and/or sold, up
17 through and including the present.

18 **Response to Interrogatory No. 1:**

19 NNI incorporates, as if fully set forth herein, the General Objections by reference.
20 NNI further objects to this interrogatory to the extent that it seeks information about
21 Victoza's® manufacture as it is neither relevant nor reasonably calculated to lead to the
22 discovery of admissible evidence because Plaintiffs did not allege manufacturing defect
23 of Victoza® in this litigation. NNI further objects to this interrogatory to the extent it
24 seeks information about the manufacture, marketing, testing, creation, distribution,
25 packaging, or promotion of Victoza® outside of the United States because it is neither
26 relevant nor reasonably calculated to lead to the discovery of admissible evidence, and is
27 unduly burdensome to produce in this litigation. NNI further objects to the extent this
28 interrogatory seeks third-party private, confidential, proprietary, or competitively

1 sensitive or trade secret information. NNI further objects to the extent this interrogatory
2 seeks legal conclusions.

3 Subject to and without waiving or otherwise limiting the foregoing general and
4 specific objections, NNI states that Novo Nordisk Inc. marketed, distributed, promoted
5 and sold Victoza® in the United States from its FDA approval in 2010 through current
6 date. NNI further states that it has engaged in agreements with third party entities to
7 distribute Victoza® within the U.S. NNI will meet and confer with Plaintiffs regarding a
8 further response if needed regarding, among other things, the appropriate scope and
9 context of this request.

10
11 **Reason Why the Answer Should be Provided:**

12 Entities engaged in creation, marketing (to doctors), testing and packaging
13 (including package inserts) are sources of discoverable information on science and
14 general causation issues. Defendant relies on foreign studies and activities (including
15 EMA), and cannot shield from foreign discovery.

16
17
18 **Basis for Nondisclosure:**

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20 **INTERROGATORY NO. 2:**

21 Describe in detail the relationship between and among Defendant and any other
22 companies or other entities that manufactured, marketed, tested, created, distributed,
23 packaged, promoted, and/or sold VICTOZA. Provide with your answer any
24 DOCUMENTS memorializing the agreements between and among Defendant and any
25 such companies or other entities.

26
27 **Response to Interrogatory No. 2:**

1 NNI incorporates, as if fully set forth herein, the General Objections by reference.
2 NNI further objects to this interrogatory to the extent that it seeks information about
3 Victoza's® manufacture as it is neither relevant nor reasonably calculated to lead to the
4 discovery of admissible evidence because Plaintiffs did not allege manufacturing defect
5 of Victoza® in this litigation. NNI further objects to this interrogatory to the extent it
6 seeks information about the manufacture, marketing, testing, creation, distribution,
7 packaging, or promotion of Victoza® outside of the United States because it is neither
8 relevant nor reasonably calculated to lead to the discovery of admissible evidence, and is
9 unduly burdensome to produce in this litigation. NNI further objects to the extent this
10 interrogatory seeks third-party private, confidential, proprietary, or competitively
11 sensitive or trade secret information. NNI further objects to the extent this interrogatory
12 seeks legal conclusions.

13 Subject to and without waiving or otherwise limiting the foregoing general and
14 specific objections, NNI states that it has engaged in agreements with third party entities
15 to distribute Victoza® within the U.S. NNI will meet and confer with Plaintiffs regarding
16 a further response if needed regarding, among other things, the appropriate scope and
17 context of this request.

18
19 **Reason Why the Answer Should be Provided:**

20 These relationships and the contracts that formalize them are key to understanding
21 who did what and where defendant's science and general causation documentation is
22 located. These entities are sources of discoverable information on science and general
23 causation issues. Defendant relies on foreign studies and activities (including EMA), and
24 cannot shield itself from foreign discovery.

25
26 **Basis for Nondisclosure:**
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1 **INTERROGATORY NO. 3:**

2 Identify all license agreements and/or development agreements with any person
3 and/or entity concerning VICTOZA, and produce a copy of any written agreement.

4 **Response to Interrogatory No. 3:**

5 NNI incorporates, as if fully set forth herein, the General Objections by reference.
6 NNI objects to this interrogatory as overbroad, unduly burdensome and not reasonably
7 calculated to lead to the discovery of admissible evidence. NNI further objects to this
8 interrogatory because the terms “any person and/or entity,” are broad and ambiguous.
9

10 **Reason Why the Answer Should be Provided:**

11 These agreements are key to understanding who did what and where defendant’s
12 science and general causation documentation is located. If defendant actually performed
13 all of its own research; pre-clinical, clinical and other studies of the drug and its
14 mechanisms of action; and handled all of its regulatory filings and all other science and
15 causation-related matters completely on its own with no license agreements and/or
16 development agreements with anyone, it could easily have stated as much. That is not
17 likely to be the case, and to the extent such entities exist, they are sources of discoverable
18 information on science and general causation issues. A responsive answer is needed.
19

20 **Basis for Nondisclosure:**

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22 **INTERROGATORY NO. 4:**

23 Identify the names and state the present and/or last known address(es) of the
24 individual(s)/employee(s) with the most knowledge pertaining to VICTOZA, including
25 but not limited to:

- 26 a. The Product managers at all times Defendant manufactured, produced,
27 promoted, formulated, created, designed, sold and/or tested VICTOZA,
28 identifying the individuals by time period;

- 1 b. The sales representatives (whether nationally, regionally, etc.) at all times
2 Defendant manufactured, produced, promoted, formulated, created,
3 designed, sold and/or tested VICTOZA, identifying the individuals by
4 time period;
- 5 i. If the sales representative was a regional position, please identify
6 all regions that Defendant utilized and the person(s) most
7 knowledgeable for each specific region, identifying the individuals
8 by time period; and
- 9 ii. Describe the sales and marketing organizational structure utilized
10 by YOU regarding VICTOZA;
- 11 c. The safety and compliance individuals in charge of reporting ADVERSE
12 EVENTS and complaints of side effects to the FDA or any other agency,
13 and investigating all ADVERSE EVENTS and complaints of side effects
14 at all times Defendant manufactured, produced, promoted, formulated,
15 created, designed, sold and/or tested VICTOZA, identifying the
16 individuals by time period;
- 17 d. The person or persons at all times responsible for Quality Assurance with
18 regard to VICTOZA;
- 19 e. Defendant's liaison(s) to the FDA, whether or not part of the regulatory
20 affairs department, with regard to VICTOZA at all times Defendant
21 manufactured, produced, promoted, formulated, created, designed, sold
22 and/or tested VICTOZA, identifying the individuals by time period;
- 23 f. Defendant's researcher(s) and developer(s) responsible for VICTOZA at
24 all times Defendant manufactured, produced, promoted, formulated,
25 created, designed, sold and/or tested VICTOZA, identifying the
26 individuals by time period;
- 27
28

- 1 g. Defendant’s scientific researcher(s) of VICTOZA at all times Defendant
2 manufactured, produced, promoted, formulated, created, designed, sold
3 and/or tested VICTOZA, identifying the individuals by time period;
- 4 h. The person or persons responsible for Defendant’s marketing and/or
5 detailing of VICTOZA at all times Defendant manufactured, produced,
6 promoted, formulated, created, designed, sold and/or tested VICTOZA,
7 identifying the individuals by time period;
- 8 i. Defendant’s Chief Medical Officer at all times Defendant manufactured,
9 produced, promoted, formulated, created, designed, sold and/or tested
10 VICTOZA, identifying the individuals by time period;
- 11 j. Defendant’s Chief Executive Officer (“CEO”) at all times Defendant
12 manufactured, produced, promoted, formulated, created, designed, sold
13 and/or tested VICTOZA, identifying the individuals by time period;
- 14 k. Defendant’s President at all times Defendant manufactured, produced,
15 promoted, formulated, created, designed, sold and/or tested VICTOZA,
16 identifying the individuals by time period;
- 17 l. Defendant’s Chief Financial Officer (“CFO”) at all times Defendant
18 manufactured, produced, promoted, formulated, created, designed, sold
19 and/or tested VICTOZA, identifying the individuals by time period;
- 20 m. Defendant’s Chief Information Officer (“CIO”) at all times Defendant
21 manufactured, produced, promoted, formulated, created, designed, sold
22 and/or tested VICTOZA, identifying the individuals by time period;
- 23 n. The person responsible for regulatory affairs at all times Defendant
24 manufactured, produced, promoted, formulated, created, designed, sold
25 and/or tested VICTOZA, identifying the individuals by time period;
- 26 o. Defendant’s liaison(s) with any subsidiary or affiliate located outside the
27 United States that manufactured, produced, promoted, formulated,
28

1 created, designed, sold and/or tested VICTOZA, identifying the
2 individuals by time period;

3 p. Defendant's General Counsel and/or the names of all associate general
4 counsel at all times Defendant manufactured, produced, promoted,
5 formulated, created, designed, sold and/or tested VICTOZA, identifying
6 the individuals by time period;

7 q. Defendant's Chief Operating Officer ("COO") at all times Defendant
8 manufactured, produced, promoted, formulated, created, designed, sold
9 and/or tested VICTOZA, identifying the individuals by time period; and

10 r. Members of any International Product Team maintained or utilized by
11 YOU at all times Defendant manufactured, produced, promoted,
12 formulated, created, designed, sold and/or tested VICTOZA, identifying
13 the individuals by time period.

14
15 **Response to Interrogatory No. 4:**

16 NNI incorporates, as if fully set forth herein, the General Objections by reference.
17 NNI further objects to this interrogatory as vague and ambiguous as it fails to define
18 certain terms and phrases, including "complaints of side effects," "liaison,"
19 "responsible," and "detailing." NNI further objects to this interrogatory to the extent that
20 it seeks information about Victoza's® manufacture as it is neither relevant nor reasonably
21 calculated to lead to the discovery of admissible evidence because Plaintiffs did not
22 allege manufacturing defect of Victoza® in this litigation. NNI further objects to the
23 extent this interrogatory seeks information concerning activities outside the United
24 States. NNI objects further to this interrogatory to the extent it requests public
25 information. NNI objects further to this interrogatory to the extent that it seeks
26 information about Victoza® sales representatives more appropriate for case-specific
27 discovery. NNI objects further to this interrogatory to the extent that it seeks information
28 about Victoza's® International Product Team.

1 Subject to and without waiving or otherwise limiting the foregoing general and
2 specific objections, NNI refers Plaintiffs to the organizational charts that will be
3 produced by NNI in this litigation. In addition, pursuant to the parties' agreement on
4 February 3, 2014, NNI will answer this interrogatory more fully at a later time, as
5 needed, once its discovery and document production are more substantially completed
6 and upon mutual agreement by the parties regarding, among other things, the appropriate
7 scope and context of this request.

8 **Reason Why the Answer Should be Provided:**

9 This is basic information about persons most knowledgeable (PMKs) on science
10 and causation-related issues. Plaintiffs do not believe the "burden of deriving or
11 ascertaining the answer will be substantially the same" for them as for defendant just by
12 reviewing organization charts, as required by Rule 33(d). However, that is not an issue
13 because no charts have even been identified. The notion that such basic information
14 about science issues can be identified "later" is fanciful under the new "science first"
15 scheduling order. Time – and the quality of the information provided – is of the essence.
16

17 **Basis for Nondisclosure:**

18
19 **INTERROGATORY NO. 5:**

20 Identify all persons and/or entities paid by YOU for consulting services of any kind
21 concerning VICTOZA, and for each such person or entity state the nature of the
22 consulting services rendered and the time frame(s) during which they were rendered.

23 **Response to Interrogatory No. 5:**

24 NNI incorporates, as if fully set forth herein, the General Objections by reference.
25 NNI objects further to this interrogatory because the term "consulting services of any
26 kind" is overbroad, ambiguous and vague.
27

28 **Reason Why the Answer Should be Provided:**

1 If defendant actually performed all of its own research; pre-clinical, clinical and
2 other studies of the drug and its mechanisms of action; and handled all of its regulatory
3 filings and all other science and causation-related matters completely on its own without
4 the assistance of any consultants, it could easily have stated as much. That is not likely to
5 be the case, and to the extent such consultants exist, they are sources of discoverable
6 information on science and general causation issues. Plaintiffs respectfully submit that
7 the term “consulting services” – as with the other common terms defendant objects to as
8 vague throughout its responses – is reasonably clear. A responsive answer is needed.
9

10 **Basis for Nondisclosure:**

11
12 **INTERROGATORY NO. 6:**

13 Did YOU or others acting on YOUR behalf ever consult with researchers,
14 physicians, nurse scientists, public health advocates, governmental bodies, or others not
15 on your own staff about whether BYETTA, JANUVIA, JANUMET and/or VICTOZA
16 were effective and/or as effective as other therapeutic agents for the treatment of type 2
17 diabetes? If so, state: (a) how efficacy was defined; (b) the method(s) by which efficacy
18 was determined; (c) the name of each consultant; (d) the date or time periods of each
19 consultation; (e) the amounts paid to each consultant; (f) the opinions and/or findings
20 given to YOU by each consultant; (g) if those opinions and/or findings were ever
21 published, identify the name(s) and location(s) of the publication(s); and (h) if those
22 opinions and/or findings were not published, (1) explain why not, (2) state whether they
23 were written anywhere, and (3) state the location of each such writing.

24 **Response to Interrogatory No. 6:**

25 NNI incorporates, as if fully set forth herein, the General Objections by reference.
26 NNI further objects to this interrogatory because the terms “consult,” “effective,”
27 “consultant,” “opinions and/or findings” and “others not on your own staff” are
28 overbroad, vague and ambiguous. NNI further objects to the extent that this interrogatory

1 relates to or seeks information regarding products other than Victoza®. NNI further
2 objects to this interrogatory to the extent it calls for information that is not in the
3 possession, custody, or control of NNI.

4 Subject to and without waiving or otherwise limiting the foregoing general and
5 specific objections, NNI states that it will meet and confer with Plaintiffs to narrow this
6 request if needed.

7 **Reason Why the Answer Should be Provided:**

8 Any science-related information defendant has on any incretin drugs should be
9 considered relevant in this matter, as it deals with the same general class of medications.
10 Defendant's science-related work and/or comparative studies of other incretin-based
11 therapies can reasonably be expected to shed light on its own drug. The identification of
12 consultants is crucial to determining the location of discoverable documents and other
13 information. Consultant compensation is relevant to potential bias. Publication
14 information allows cross-checking actual data with published data. Failure to publish
15 studies with unfavorable outcomes is an important indicator of bias. A responsive answer
16 is needed.

17
18 **Basis for Nondisclosure:**

19
20 **INTERROGATORY NO. 7:**

21 Identify every country in which VICTOZA is or has been marketed or sold by
22 YOU and/or marketed or sold by other corporate entities pursuant to an agreement with
23 YOU, whether it was marketed or sold under the brand name VICTOZA or any other
24 name. Include in your answer: (a) the date YOU or your agents first sought regulatory
25 approval to market or sell VICTOZA in each country; (b) the date on which approval to
26 market or sell VICTOZA was granted in each country; and (c) the date on which
27 VICTOZA first became commercially available in each country.

28 **Response to Interrogatory No. 7:**

1 NNI incorporates, as if fully set forth herein, the General Objections by reference.
2 NNI objects to the extent this interrogatory seeks information related to the sale and
3 marketing of Victoza®, whether under the brand name Victoza® or any other name,
4 outside of the United States because it is neither relevant nor reasonably calculated to
5 lead to the discovery of admissible evidence and is unduly burdensome to produce in this
6 litigation. NNI further objects to this interrogatory because it requests publicly available
7 information.

8 Subject to and without waiving or otherwise limiting the foregoing general and
9 specific objections, NNI states that it submitted its New Drug Application 22- 341 to the
10 FDA on May 23, 2008 seeking approval for Victoza® to be marketed in the U.S. NNI
11 further states that Victoza® was approved for use in the U.S. by the FDA on January 25,
12 2010 and was commercially available in the U.S. on or around February 8, 2010. NNI
13 further states that it will meet and confer with Plaintiffs regarding a further response as to
14 the regulatory approval for Victoza® outside of the U.S. if needed regarding, among
15 other things, the appropriate scope and context of this request.
16

17 **Reason Why the Answer Should be Provided:**

18 Defendant relies on foreign studies, activities and regulatory bodies (including
19 EMA), and cannot shield those from discovery. The basic information requested here
20 will allow Plaintiffs to target areas for further inquiry and track changes in science and
21 causation-related issues (warnings, package inserts, etc.) over time as the drug is offered
22 for approval and approved outside the U.S. The requested information is relevant and
23 should be provided.
24

25 **Basis for Nondisclosure:**

26
27 **INTERROGATORY NO. 8:**
28

1 Did Defendant ever sell, manufacture, market, promote, test, or issue warnings
2 about side effects concerning VICTOZA outside the United States, even if the product
3 had a different name or formulation? If so, please state the countries and the dates that
4 VICTOZA or the differently named and/or formulated product was and/or is sold,
5 manufactured, marketed, promoted, or tested, and specify each country where the
6 warnings were different than those issued in the United States.

7 **Response to Interrogatory No. 8:**

8 NNI incorporates, as if fully set forth herein, the General Objections by reference.
9 NNI further objects to this interrogatory to the extent that it seeks information about
10 Victoza's® manufacture as it is neither relevant nor reasonably calculated to lead to the
11 discovery of admissible evidence because Plaintiffs did not allege manufacturing defect
12 of Victoza® in this litigation. NNI further objects to the extent this request seeks
13 information related to the sale, marketing, promotion, testing or issuance of warnings
14 about side effects of Victoza®, whether under the brand name Victoza® or any other
15 name, outside of the United States because it is neither relevant nor reasonably calculated
16 to lead to the discovery of admissible evidence and is unduly burdensome to produce in
17 this litigation.

18
19 **Reason Why the Answer Should be Provided:**

20 Defendant relies on foreign studies, activities and regulatory bodies (including
21 EMA), and cannot shield those from discovery. The basic information requested here
22 will allow Plaintiffs to target areas for further inquiry and track changes in science and
23 causation-related issues. Changes in warnings from country to country can be
24 particularly significant due to differences in the science or interpretations of the science
25 in any given location at any given time.

26
27
28 **Basis for Nondisclosure:**

1
2
3 **INTERROGATORY NO. 9:**

4 Identify the design used by YOU with respect to VICTOZA, and any changes in
5 the design of VICTOZA from the time it was first developed until the present. Include in
6 your answer the specific changes made to the design, the date of the changes, and why
7 the changes were made.

8 **Response to Interrogatory No. 9:**

9 NNI incorporates, as if fully set forth herein, the General Objections by reference.
10 NNI objects to this interrogatory to the extent it requests trade secret or confidential
11 company information. NNI objects to this interrogatory to the extent it requests
12 information related to Victoza® activities outside of the U.S.

13 Subject to and without waiving or otherwise limiting the foregoing general and
14 specific objections, NNI states that information pertaining to the design of Victoza® in
15 the U.S. can be found in NNI's submissions and communications with the FDA,
16 produced at Bates ranges NNI-IND-61040-00000001 – NNI-IND-61040-00059607 and
17 NNI-NDA-22341-00000001 – NNI-NDA-22341-01380778.

18
19 **Reason Why the Answer Should be Provided:**

20 The answer to this basic question should be relatively straightforward, but
21 defendant provides only a document dump of 59,607 + 1,380,778 pages. Plaintiffs do not
22 believe the “burden of deriving or ascertaining the answer will be substantially the same”
23 for them as for defendant, as required by Rule 33(d), if they have to read every page to
24 get the answer to this question. The design and any changes should either be spelled out
25 in a responsive answer or the specific documents containing that information should be
26 targeted by Bates number.
27
28

1 **Basis for Nondisclosure:**

2
3 **INTERROGATORY NO. 10:**

4 Identify each and every database that YOU or others acting on YOUR behalf
5 maintain or have maintained that is likely to contain any data or information about
6 BYETTA, JANUVIA, JANUMET, VICTOZA and/or any other GLP-1 agonist or DPP-4
7 inhibitor. Include in your answer:

- 8 a. The name of each database;
- 9 b. The identity of the database administrators;
- 10 c. The dates of use for each database;
- 11 d. The hardware and software platforms each database utilized;
- 12 e. The type of information about BYETTA, JANUVIA, JANUMET,
13 VICTOZA, and/or any other GLP-1 agonist or DPP-4 inhibitor contained
14 in each database;
- 15 f. Whether each database was a transactional database;
- 16 g. Whether each database was a warehouse database;
- 17 h. The identity of all other databases that fed information into each database
18 identified;
- 19 i. The search capabilities of each database;
- 20 j. The back-up schedule for each database;
- 21 k. Whether each database has an audit trail feature that has been enabled;
- 22 l. The archival, retention and destruction policies with respect to each
23 database; and,
- 24 m. Whether any database has been discontinued and what was done with the
25 data contained in any retired database.

26 **Response to Interrogatory No. 10:**

27 NNI incorporates, as if fully set forth herein, the General Objections by reference.
28 NNI objects to this interrogatory because it is overly broad and unduly burdensome. NNI

1 further objects to this interrogatory as vague and ambiguous as it fails to define certain
2 terms and phrases, including “transactional database,” and “warehouse database.” NNI
3 further objects to the extent that this interrogatory relates to or seeks information
4 regarding products other than Victoza®.

5 Subject to and without waiving or otherwise limiting the foregoing general and
6 specific objections, and pursuant to the parties’ agreement on February 3, 2014, NNI will
7 answer this interrogatory more fully at a later time, as needed, once its discovery and
8 document production are more substantially completed and upon mutual agreement by
9 the parties regarding, among other things, the appropriate scope and context of this
10 request.

11
12 **Reason Why the Answer Should be Provided:**

13 Detailed information about drug company databases is essential for tracking down
14 adverse event data, study data, scientific research and other information about a
15 defendant’s drug. The databases are the repositories of information sent and not sent to
16 the FDA. They may have very sophisticated search capabilities that can be used to sort
17 and/or retrieve information, potentially including information not previously made
18 available to the scientific community. A fully responsive answer can and should be
19 developed by defendant’s IT department, since they will be most familiar with the
20 structure and capabilities of the company’s databases housing information about incretin-
21 based drug therapies. Plaintiffs can target further discovery more precisely based on
22 what drug-related information is known to be stored in which databases, but they first
23 need the database information.

24
25 **Basis for Nondisclosure:**

26
27 **INTERROGATORY NO. 11:**

1 Have YOU ever had a document retention policy, document destruction policy, or
2 document archiving policy? If so, describe each such policy, indicating the applicable
3 time frames for each policy.

4 **Response to Interrogatory No. 11:**

5 NNI incorporates, as if fully set forth herein, the General Objections by reference.
6 NNI objects to this interrogatory to the extent it is requesting information not related to
7 Victoza® or the injuries at issue in this litigation. NNI further objects to this
8 interrogatory to the extent that it is overly broad, unduly burdensome and not reasonably
9 calculated to lead to the discovery of admissible evidence.

10 Subject to and without waiving or otherwise limiting the foregoing general and
11 specific objections, and pursuant to the parties' agreement on February 3, 2014, NNI will
12 answer this interrogatory more fully at a later time, as needed, once its discovery and
13 document production are more substantially completed and upon mutual agreement by
14 the parties regarding, among other things, the appropriate scope and context of this
15 request.

16
17 **Reason Why the Answer Should be Provided:**

18 Plaintiffs need to know what documents may have been destroyed and when, what
19 should still be preserved, and where to look for it. This is routine discovery that should
20 have been provided from the get-go.

21
22 **Basis for Nondisclosure:**

23
24 **INTERROGATORY NO. 13:**

25 Have YOU performed or had performed on YOUR behalf any animal studies in
26 which the safety, side effects, and/or efficacy of VICTOZA was tested or otherwise
27 documented? If so, please state the following:

- 28 a. When was the first time such a study was made by or for YOU;

- 1 b. How many studies were done by or for YOU, and state the inclusive
2 dates of each study;
- 3 c. Why each study was done;
- 4 d. Identify the type(s) of animal(s) tested, and state the number of animals
5 involved in each study;
- 6 e. Why the particular test animal was selected for each study;
- 7 f. What dosage of VICTOZA was selected for each study;
- 8 g. Why the particular dosage of VICTOZA was selected for each study;
- 9 h. What comparator drug or drugs, if any, were used for each study;
- 10 i. Why the particular comparator drug or drugs, if any, were used for each
11 study;
- 12 j. Whether the studies were completed and whether the data was ever
13 published; if the data was published, identify the date, publication, and
14 authors; and if the data was not published, state why not; and
- 15 k. Whether the study results were submitted to the FDA and, if so, state the
16 date on which it was submitted and identify the Bates number of any
17 cover letter accompanying the submission.

18 **Response to Interrogatory No. 13:**

19 NNI incorporates, as if fully set forth herein, the General Objections by reference.
20 NNI objects to this interrogatory as overly broad and unduly burdensome. NNI further
21 objects to this interrogatory to the extent it requests publicly available information. NNI
22 further objects to this interrogatory to the extent it requests NNI to review studies that
23 Plaintiffs can review themselves. NNI further objects to this interrogatory to the extent it
24 request information duplicative of a 30(b)(6) request served on NNI in this litigation.
25 NNI further objects to the extent that this interrogatory relates to or seeks information
26 regarding products other than Victoza®.

27 Subject to and without waiving the foregoing objections, NNI states that it will
28 produce a chart identifying its completed and ongoing non-clinical studies for Victoza®

1 that were conducted by NNI that have been identified at this time. NNI further states it
2 will produce protocols and final study reports, to the extent available, for its completed
3 and ongoing non-clinical studies for Victoza® that were conducted by NNI that have
4 been identified at this time. NNI further refers Plaintiffs to NNI’s submissions and
5 communications with the FDA, produced at Bates ranges NNI-IND-61040-00000001 –
6 NNI-IND-61040-00059607 and NNI-NDA-22341-00000001 – NNI-NDA-22341-
7 01380778. NNI further states that it will meet and confer over the production of
8 additional responsive data and information if needed regarding, among other things, the
9 appropriate scope and context of this request.
10

11 **Reason Why the Answer Should be Provided:**

12 Animal studies are basic information in drug cases and the information requested
13 here should have been provided long ago. Instead, defendant provides only a document
14 dump of 59,607 + 1,380,778 pages. Plaintiffs do not believe the “burden of deriving or
15 ascertaining the answer will be substantially the same” for them as for defendant, as
16 required by Rule 33(d), if they have to read every page to get the answers to this question
17 and its subparts.

- 18 • Information about publication or lack of publication is important and may not be
19 apparent from the study data itself. The same is true with respect to whether the
20 study was sent to the FDA.
- 21 • If defendant has actually made all of the information requested in this interrogatory
22 publically available, it should state with precision where it is available.
- 23 • It is unclear from defendant’s objections whether it is attempting to limit its
24 response just to studies “conducted” by NNI, as opposed to all studies even if they
25 were conducted by others. All studies should be discoverable, not just those done
26 directly by NNI.

- 1 • If defendant has already provided a complete answer to this question in the form of
2 a response to a 30(b)(6) request, it could have easily said so and pointed Plaintiffs
3 directly to that information. It did not. A responsive answer should be provided.
4

5 **Basis for Nondisclosure:**
6

7 **INTERROGATORY NO. 14:**

8 Identify all pre-approval or post-approval clinical trials or other studies that were
9 conducted by YOU or on YOUR behalf (whether completed or not) concerning
10 VICTOZA, pursuant to an Investigational New Drug (“IND”) Application, New Drug
11 Application (“NDA”), Supplemental New Drug Application (“SNDA”), or Abbreviated
12 New Drug Application (“ANDA”) or conducted for any other reason and, with respect to
13 each such trial or study, state:

- 14 a. The protocol number and study name;
15 b. The names and addresses of all clinical investigation sites;
16 c. The names and addresses of all clinical investigators, including any
17 medical institution they are affiliated with;
18 d. The names and addresses of all sponsor-investigators;
19 e. The names and addresses of all contract research organizations;
20 f. Whether the studies have been concluded;
21 g. The duration of each study;
22 h. The Bates number for each final study report and each study protocol;
23 i. A description of what each study concerned, and the results of each
24 study;
25 j. The identity of each person responsible for maintaining the records
26 regarding these studies;
27 k. Whether any study was terminated before it was fully completed, and if
28 so state why;

- 1 l. Whether any studies have been terminated at the request and/or the
2 demand of the FDA;
- 3 m. Whether the study was submitted for publication and, if so, whether it
4 was accepted for publication;
- 5 n. The citation to any published study;
- 6 o. The date that the data from each study was “locked” and the date that the
7 data was unblended;
- 8 p. The number of patients enrolled in each study and the number of patients
9 who completed each study;
- 10 q. Identify those studies that were designed to test the safety of VICTOZA;
- 11 r. Identify those studies that were designed to test the efficacy of
12 VICTOZA;
- 13 s. Whether the FDA has ever lodged any complaints, warnings, or
14 reprimands with respect to the conduct of any of the studies;
- 15 t. All amendments to any study protocol and the reason why the protocol
16 was amended;
- 17 u. Whether any human tissue was obtained as part of any study and, if so,
18 identify the study and state the location of the tissue;
- 19 v. If an animal study, state the type of animal used in the study;
- 20 w. Whether any animal tissue was obtained as part of any study and, if so,
21 identify the study and state the location of the tissue;
- 22 x. Whether any animal pancreatic tissue was obtained as part of any study
23 and, if so, identify the study and state the location of the tissue;
- 24 y. Whether any pancreatic islet cell hyperplasia was diagnosed in any
25 animal study and, if so, identify the study and state the location of the
26 tissue;
- 27 z. Whether any pancreatic duct inflammation was diagnosed in any animal
28 study and, if so, identify the study and state the location of the tissue;

- 1 aa. Whether any PanIN lesions were diagnosed in any animal study and, if
2 so, identify the study and state the location of the tissue;
3 bb. Whether any nesidioblastosis was diagnosed in any animal study and, if
4 so, identify the study and state the location of the tissue;
5 cc. Whether any animal thyroid tissue was obtained as part of any study and,
6 if so, identify the study and state the location of the tissue;
7 dd. The Bates number for all informed consent forms;
8 ee. Identify who has custody of the protocols followed in each study;
9 ff. Identify all records and data from, reflecting and/or relating to each such
10 study; and,
11 gg. Whether the study results were submitted to the FDA and, if so, the date
12 on which they were submitted and the Bates number of any cover letter
13 accompanying the submissions.
14

15 **Response to Interrogatory No. 14:**

16 NNI incorporates, as if fully set forth herein, the General Objections by reference.
17 NNI objects to this interrogatory as overly broad and unduly burdensome. NNI further
18 objects to this interrogatory to the extent it requests publicly available information. NNI
19 further objects to this interrogatory to the extent it requests NNI to review studies that
20 Plaintiffs can review themselves. NNI further objects to this interrogatory to the extent it
21 request information duplicative of a 30(b)(6) request served on NNI in this litigation.
22 NNI further objects to the extent that this interrogatory relates to or seeks information
23 regarding products other than Victoza®.

24 Subject to and without waiving the foregoing objections, NNI states that it will
25 produce charts identifying its completed and ongoing non-clinical and clinical studies for
26 Victoza® that were conducted by NNI that have been identified at this time. NNI further
27 states it will produce protocols and final study reports, to the extent available, for its
28 completed and ongoing non-clinical and clinical studies for Victoza® that were

1 conducted by NNI that have been identified at this time. NNI further states that it will
2 produce data sets, to the extent available, for its completed and ongoing clinical studies
3 for Victoza® that were conducted by NNI that have been identified at this time. NNI
4 further refers Plaintiffs to NNI's submissions and communications with the FDA,
5 produced at Bates ranges NNI-IND-61040-00000001 – NNI-IND-61040-00059607 and
6 NNI-NDA-22341-00000001 – NNI-NDA-22341-01380778. NNI further states that it will
7 meet and confer over the production of additional responsive data and information.
8

9 **Reason Why the Answer Should be Provided:**

10 Pre-approval and post-approval clinical trials and other similar studies are basic
11 information in drug cases and the information requested here should have been provided
12 long ago. Instead, defendant provides only a document dump of 59,607 + 1,380,778
13 pages. Plaintiffs do not believe the “burden of deriving or ascertaining the answer will be
14 substantially the same” for them as for defendant, as required by Rule 33(d), if they have
15 to read every page to get the answers to this question and its subparts.

- 16 • Information about publication, lack of publication and the information requested in
17 a number of other subparts is important and may not be apparent from the study
18 data itself.
- 19 • If defendant has actually made all of the information requested in this interrogatory
20 publically available, it should state with precision where it is available.
- 21 • It is unclear from defendant's objections whether it is attempting to limit its
22 response just to studies “conducted” by NNI, as opposed to all studies even if they
23 were conducted by others. All studies should be discoverable, not just those done
24 directly by NNI.
- 25 • Any science-related information defendant has on any incretin drugs should be
26 considered relevant in this matter, as it deals with the same general class of
27 medications. Defendant's science-related work and/or comparative studies of
28

1 other incretin-based therapies can reasonably be expected to shed light on its own
2 drug.

- 3 • If defendant has already provided a complete answer to this question in the form of
4 a response to a 30(b)(6) request, it could have easily said so and pointed Plaintiffs
5 directly to that information. It did not. A responsive answer should be provided.
6

7 **Basis for Nondisclosure:**

8
9 **Interrogatory No. 15:**

10 Identify all clinical trials or other studies that were conducted by YOU or on
11 YOUR behalf (whether completed or not) concerning any product (whether or not it was
12 ever approved for marketing or submitted to any Regulatory Authority for such approval)
13 containing exenatide, sitagliptin, liraglutide and/or any other GLP-1 agonist or DPP-4
14 inhibitor as one of its components and, with respect to each such trial or study, state:

- 15 a. The names and addresses of all clinical investigation sites;
- 16 b. The names and addresses of all clinical investigators;
- 17 c. The names and addresses of all sponsor-investigators;
- 18 d. The names and addresses of all contract research organizations;
- 19 e. Whether such studies have been concluded;
- 20 f. A description of what each study concerned, and the results of each such
21 study;
- 22 g. The identity of each person responsible for maintaining the records
23 regarding these studies;
- 24 h. Whether any study was terminated before it was fully completed and, if
25 so, state why;
- 26 i. Whether any studies have been terminated at the request and/or the
27 demand of the FDA;
- 28

- 1 j. Whether the FDA has ever lodged any complaints, warnings, or
2 reprimands with respect to the conduct of any of the studies;
- 3 k. Identify who has custody of the protocols followed in each study;
- 4 l. Identify all records and data from, reflecting and/or relating to each such
5 study; and,
- 6 m. Whether the study results were submitted to the FDA and, if so, the date
7 on which they were submitted and the Bates number of any cover letter
8 accompanying the submissions.
- 9

10 **Response to Interrogatory No. 15:**

11 NNI incorporates, as if fully set forth herein, the General Objections by reference.
12 NNI objects to this interrogatory as overly broad and unduly burdensome. NNI further
13 objects to this interrogatory to the extent it requests publicly available information. NNI
14 further objects to this interrogatory to the extent it requests NNI to review studies that
15 Plaintiffs can review themselves. NNI further objects to this interrogatory to the extent it
16 request information duplicative of a 30(b)(6) request served on NNI in this litigation.
17 NNI further objects to the extent that this interrogatory relates to or seeks information
18 regarding products other than Victoza®.

19 Subject to and without waiving the foregoing objections, NNI states that it will
20 produce a chart identifying its completed and ongoing clinical studies for Victoza® that
21 were conducted by NNI. NNI further states it will produce protocols and final study
22 reports, to the extent available, for its completed and ongoing clinical studies for
23 Victoza® that were conducted by NNI that have been identified at this time. NNI further
24 states that it will produce data sets, to the extent available, for its completed and ongoing
25 clinical studies for Victoza® that were conducted by NNI that have been identified at this
26 time. NNI further refers Plaintiffs to NNI's submissions and communications with the
27 FDA, produced at Bates ranges NNI-IND-61040-00000001– NNI-IND-61040-00059607
28 and NNI-NDA-22341-00000001 – NNI-NDA-22341-01380778. NNI further states that it

1 will meet and confer over the production of additional responsive data and information if
2 needed regarding, among other things, the appropriate scope and context of this request.
3

4 **Reason Why the Answer Should be Provided:**

5 Clinical trials and other studies performed on incretin-based therapy drugs are
6 basic information in this case and the information requested here should have been
7 provided long ago. Instead, defendant provides only a document dump of 59,607 +
8 1,380,778 pages. Plaintiffs do not believe the “burden of deriving or ascertaining the
9 answer will be substantially the same” for them as for defendant, as required by Rule
10 33(d), if they have to read every page to get the answers to this question and its subparts.

- 11 • Information about publication, lack of publication and the information requested in
12 a number of other subparts is important and may not be apparent from the study
13 data itself.
- 14 • If defendant has actually made all of the information requested in this interrogatory
15 publically available, it should state with precision where it is available.
- 16 • It is unclear from defendant’s objections whether it is attempting to limit its
17 response just to studies “conducted” by NNI, as opposed to all studies even if they
18 were conducted by others. All studies should be discoverable, not just those done
19 directly by NNI.
- 20 • Any science-related information defendant has on any incretin drugs should be
21 considered relevant in this matter, as it deals with the same general class of
22 medications. Defendant’s science-related work and/or comparative studies of
23 other incretin-based therapies can reasonably be expected to shed light on its own
24 drug.
- 25 • If defendant has already provided a complete answer to this question in the form of
26 a response to a 30(b)(6) request, it could have easily said so and pointed Plaintiffs
27 directly to that information. It did not. A responsive answer should be provided.
28

1 **Basis for Nondisclosure:**
2
3

4 **INTERROGATORY NO. 16:**

5 Please identify and describe all tests, investigations, studies, evaluations and/or
6 assessments conducted by YOU or on YOUR behalf, and/or relied upon by YOU either
7 in whole or in part, relating in any way to BYETTA, JANUVIA, JANUMET and/or
8 VICTOZA and pancreatitis and/or pancreatic cancer, including:

- 9 a. If published, the exact title, author, publisher, place of publication, and
10 year of publication of any such test, investigation, study, evaluation
11 and/or assessment;
- 12 b. The dates that each such test, investigation, study, evaluation and/or
13 assessment was conducted;
- 14 c. The name and job title of each of YOUR employees, agents and/or
15 servants, if any, who were responsible for the performance and/or
16 evaluation of, and/or were in any way involved with the performance
17 and/or evaluation of, each such test, investigation, study, evaluation
18 and/or assessment;
- 19 d. Whether the individuals identified in sub-paragraph (c) above are still
20 employed by YOU and, if not, their last known address;
- 21 e. A step-by-step description of the methodology of each such test,
22 investigation, study, evaluation and/or assessment;
- 23 f. The purpose of each such test, investigation, study, evaluation and/or
24 assessment;
- 25 g. The full and complete verbatim results of each such test, investigation,
26 study, evaluation and/or assessment;
- 27 h. All raw data for each such test, investigation, study, evaluation and/or
28 assessment;

- 1 i. The date, manner, and means by which YOU first became aware of each
2 such test, investigation, study, evaluation and/or assessment; and,
3 j. Whether such data from each such test, investigation, study, evaluation
4 and/or assessment was submitted to the FDA, and if so, on what date.
5
6

7 **Response to Interrogatory No. 16:**

8 NNI incorporates, as if fully set forth herein, the General Objections by reference.
9 NNI objects to this interrogatory as overly broad and unduly burdensome. NNI further
10 objects to this interrogatory to the extent it requests publicly available information. NNI
11 further objects to this interrogatory to the extent it requests NNI to review studies that
12 Plaintiffs can review themselves. NNI further objects to this interrogatory to the extent it
13 request information duplicative of a 30(b)(6) request served on NNI in this litigation.
14 NNI further objects to the extent that this interrogatory relates to or seeks information
15 regarding products other than Victoza®.

16 Subject to and without waiving the foregoing objections, NNI states that it will
17 produce charts identifying its completed and ongoing non-clinical and clinical studies for
18 Victoza® that were conducted by NNI that have been identified at this time. NNI further
19 states it will produce protocols and final study reports, to the extent available, for its
20 completed and ongoing non-clinical and clinical studies for Victoza® that were
21 conducted by NNI that have been identified at this time. NNI further states that it will
22 produce data sets, to the extent available, for its completed and ongoing clinical studies
23 for Victoza® that were conducted by NNI that have been identified at this time. NNI
24 further refers Plaintiffs to NNI's submissions and communications with the FDA,
25 produced at Bates ranges NNI-IND-61040-00000001 – NNI-IND-61040-00059607 and
26 NNI-NDA-22341-00000001 – NNI-NDA-22341-01380778. NNI further states that it will
27 meet and confer over the production of additional responsive data and information if
28 needed regarding, among other things, the appropriate scope and context of this request.

1
2 **Reason Why the Answer Should be Provided:**

3 The information requested in this interrogatory regarding incretin-based therapy
4 drugs is basic information in this case and should have been provided long ago. Instead,
5 defendant provides only a document dump of 59,607 + 1,380,778 pages. Plaintiffs do not
6 believe the “burden of deriving or ascertaining the answer will be substantially the same”
7 for them as for defendant, as required by Rule 33(d), if they have to read every page to
8 get the answers to this question and its subparts.

- 9
- 10 • Information about publication, lack of publication and the information requested in
11 a number of other subparts is important and may not be apparent from the study
12 data itself.
 - 13 • If defendant has actually made all of the information requested in this interrogatory
14 publically available, it should state with precision where it is available.
 - 15 • It is unclear from defendant’s objections whether it is attempting to limit its
16 response just to studies “conducted” by NNI, as opposed to all studies even if they
17 were conducted by others. All studies should be discoverable, not just those done
18 directly by NNI.
 - 19 • Any science-related information defendant has on any incretin drugs should be
20 considered relevant in this matter, as it deals with the same general class of
21 medications. Defendant’s science-related work and/or comparative studies of
22 other incretin-based therapies can reasonably be expected to shed light on its own
23 drug.
 - 24 • If defendant has already provided a complete answer to this question in the form of
25 a response to a 30(b)(6) request, it could have easily said so and pointed Plaintiffs
26 directly to that information. It did not. A responsive answer should be provided.

27 **Basis for Nondisclosure:**
28

1
2 **INTERROGATORY NO. 17:**

3 From the date YOU first developed, designed, manufactured, distributed, sold,
4 and/or made VICTOZA available to consumers up through the present, identify all
5 studies YOU relied on, if any, as proof of the safety and/or efficacy of VICTOZA, and/or
6 the relative safety and/or efficacy of VICTOZA compared to other diabetes medications.
7 As to each such published study, identify the study by title, author, publication, and year
8 of publication. If any unpublished study was involved, state the title of such unpublished
9 study and the date YOU received its results. For each study, also provide:

- 10 a. If the study was not published, explain why not;
11 b. For studies undertaken by YOU, the date YOU first undertook each such
12 study;
13 c. The name and title of each of YOUR employee(s) and/or agent(s) who
14 were responsible and/or involved with each such study, and state whether
15 they are still employed by YOU, and if not, provide their last known
16 addresses and phone numbers; and
17 d. Produce all raw data for each study in native electronic format.
18

19 **Response to Interrogatory No. 17:**

20 NNI incorporates, as if fully set forth herein, the General Objections by reference.
21 NNI objects to this interrogatory as overly broad and unduly burdensome. NNI further
22 objects to this interrogatory to the extent it requests publicly available information. NNI
23 further objects to this interrogatory to the extent it requests NNI to review studies that
24 Plaintiffs can review themselves. NNI further objects to this interrogatory to the extent it
25 request information duplicative of a 30(b)(6) request served on NNI in this litigation.
26 NNI further objects to the extent that this interrogatory relates to or seeks information
27 regarding products other than Victoza®.
28

1 Subject to and without waiving the foregoing objections, NNI states that it will
2 produce charts identifying its completed and ongoing non-clinical and clinical studies for
3 Victoza® that were conducted by NNI that have been identified at this time. NNI further
4 states it will produce protocols and final study reports, to the extent available, for its
5 completed and ongoing non-clinical and clinical studies for Victoza® that were
6 conducted by NNI that have been identified at this time. NNI further states that it will
7 produce data sets, to the extent available, for its completed and ongoing clinical studies
8 for Victoza® that were conducted by NNI that have been identified at this time. NNI
9 further refers Plaintiffs to NNI's submissions and communications with the FDA,
10 produced at Bates ranges NNI-IND-61040-00000001 – NNI-IND-61040-00059607 and
11 NNI-NDA-22341-00000001 – NNI-NDA-22341-01380778. NNI further states that it will
12 meet and confer over the production of additional responsive data and information if
13 needed regarding, among other things, the appropriate scope and context of this request.
14

15 **Reason Why the Answer Should be Provided:**

16 The information requested in this interrogatory regarding incretin-based therapy
17 drugs is basic information in this case and should have been provided long ago. Instead,
18 defendant provides only a document dump of 59,607 + 1,380,778 pages. Plaintiffs do not
19 believe the “burden of deriving or ascertaining the answer will be substantially the same”
20 for them as for defendant, as required by Rule 33(d), if they have to read every page to
21 get the answers to this question and its subparts.

- 22 • Information about publication, lack of publication and the information requested in
23 a number of other subparts is important and may not be apparent from the study
24 data itself.
- 25 • If defendant has actually made all of the information requested in this interrogatory
26 publically available, it should state with precision where it is available.
- 27 • It is unclear from defendant's objections whether it is attempting to limit its
28 response just to studies “conducted” by NNI, as opposed to all studies even if they

1 were conducted by others. All studies should be discoverable, not just those done
2 directly by NNI.

- 3 • Any science-related information defendant has on any incretin drugs should be
4 considered relevant in this matter, as it deals with the same general class of
5 medications. Defendant's science-related work and/or comparative studies of
6 other incretin-based therapies can reasonably be expected to shed light on its own
7 drug.
- 8 • If defendant has already provided a complete answer to this question in the form of
9 a response to a 30(b)(6) request, it could have easily said so and pointed Plaintiffs
10 directly to that information. It did not. A responsive answer should be provided.
11

12 **Basis for Nondisclosure:**

13
14
15 **INTERROGATORY NO. 18:**

16 From the date YOU first developed, designed, manufactured, distributed, sold, and/or
17 made VICTOZA available to consumers up through the present, identify all studies YOU
18 relied on, if any, as proof that the use of the exenatide, sitagliptin, liraglutide and/or any
19 other GLP-1 agonist or DPP-4 inhibitor in VICTOZA is as safe as other diabetes
20 medications, specifically indicating which studies, if any, show the following:

- 21 a. That exenatide, sitagliptin, liraglutide and/or any other GLP-1 agonist or
22 DPP-4 inhibitor is safe;
- 23 b. That exenatide, sitagliptin, liraglutide and/or any other GLP-1 agonist or
24 DPP-4 inhibitor does not cause cancer at a higher rate than any other
25 therapeutic agents for the treatment of type 2 diabetes;
- 26 c. That exenatide, sitagliptin, liraglutide and/or any other GLP-1 agonist or
27 DPP-4 inhibitor does not cause pancreatitis at a higher rate than any other
28 therapeutic agents for the treatment of type 2 diabetes;

- 1 d. That exenatide, sitagliptin, liraglutide and/or any other GLP-1 agonist or
2 DPP-4 inhibitor does not cause pancreatic cancer at a higher rate than any
3 other therapeutic agents for the treatment of type 2 diabetes;
4 e. That exenatide, sitagliptin, liraglutide and/or any other GLP-1 agonist or
5 DPP-4 inhibitor does not cause death at a higher rate than any other
6 therapeutic agents for the treatment of type 2 diabetes; and
7 f. That exenatide, sitagliptin, liraglutide and/or any other GLP-1 agonist or
8 DPP-4 inhibitor does not cause any other severe personal injuries at a
9 higher rate than any other therapeutic agents for the treatment of type 2
10 diabetes.

11 As to each such study YOU identify in response to this interrogatory, if the study was
12 published, state the study's exact title, author, publisher, place of publication, and year of
13 publication; if the study was not published, explain why not and state the title of such
14 unpublished study and the date you received its results; state the date YOU first
15 undertook each such study; state the name and title of each of YOUR employee(s) and/or
16 agent(s) who were responsible for and/or involved with each study, and if such
17 employees are not still employed by YOU, provide their last known addresses and phone
18 numbers; and provide all raw data for each study in native electronic format.
19

20 **Response to Interrogatory No. 18:**

21 NNI incorporates, as if fully set forth herein, the General Objections by reference.
22 NNI objects to this interrogatory as overly broad and unduly burdensome. NNI further
23 objects to this interrogatory to the extent it requests publicly available information. NNI
24 further objects to this interrogatory to the extent it requests NNI to review studies that
25 Plaintiffs can review themselves. NNI further objects to this interrogatory to the extent it
26 request information duplicative of a 30(b)(6) request served on NNI in this litigation.
27 NNI further objects to the extent that this interrogatory relates to or seeks information
28 regarding products other than Victoza®.

1 Subject to and without waiving the foregoing objections, NNI states that it will
2 produce charts identifying its completed and ongoing non-clinical and clinical studies for
3 Victoza® that were conducted by NNI that have been identified at this time. NNI further
4 states it will produce protocols and final study reports, to the extent available, for its
5 completed and ongoing non-clinical and clinical studies for Victoza® that were
6 conducted by NNI that have been identified at this time. NNI further states that it will
7 produce data sets, to the extent available, for its completed and ongoing clinical studies
8 for Victoza® that were conducted by NNI that have been identified at this time. NNI
9 further refers Plaintiffs to NNI's submissions and communications with the FDA,
10 produced at Bates ranges NNI-IND-61040-00000001 – NNI-IND-61040-00059607 and
11 NNI-NDA-22341-00000001 – NNI-NDA-22341-01380778. NNI further states that it will
12 meet and confer over the production of additional responsive data and information if
13 needed regarding, among other things, the appropriate scope and context of this request.
14

15 **Reason Why the Answer Should be Provided:**

16 The information requested in this interrogatory regarding incretin-based therapy
17 drugs is basic information in this case and should have been provided long ago. Instead,
18 defendant provides only a document dump of 59,607 + 1,380,778 pages. Plaintiffs do not
19 believe the “burden of deriving or ascertaining the answer will be substantially the same”
20 for them as for defendant, as required by Rule 33(d), if they have to read every page to
21 get the answers to this question and its subparts.

- 22 • Information about publication, lack of publication and the information requested in
23 a number of other subparts is important and may not be apparent from the study
24 data itself.
- 25 • If defendant has actually made all of the information requested in this interrogatory
26 publically available, it should state with precision where it is available.
- 27 • It is unclear from defendant's objections whether it is attempting to limit its
28 response just to studies “conducted” by NNI, as opposed to all studies even if they

1 were conducted by others. All studies should be discoverable, not just those done
2 directly by NNI.

- 3 • Any science-related information defendant has on any incretin drugs should be
4 considered relevant in this matter, as it deals with the same general class of
5 medications. Defendant's science-related work and/or comparative studies of
6 other incretin-based therapies can reasonably be expected to shed light on its own
7 drug.
- 8 • If defendant has already provided a complete answer to this question in the form of
9 a response to a 30(b)(6) request, it could have easily said so and pointed Plaintiffs
10 directly to that information. It did not. A responsive answer should be provided.
11

12 **Basis for Nondisclosure:**

13
14
15 **INTERROGATORY NO. 19:**

16 Identify all testing that was done by YOU or on YOUR behalf, and/or relied upon
17 by YOU either in whole or in part, which indicated the following:

- 18 a. That BYETTA, JANUVIA, JANUMET, and/or VICTOZA is safe;
- 19 b. That BYETTA, JANUVIA, JANUMET and/or VICTOZA does not cause
20 cancer at a higher rate than any other therapeutic agents for the treatment
21 of type 2 diabetes;
- 22 c. That BYETTA, JANUVIA, JANUMET and/or VICTOZA does not cause
23 pancreatitis at a higher rate than any other therapeutic agents for the
24 treatment of type 2 diabetes;
- 25 d. That BYETTA, JANUVIA, JANUMET and/or VICTOZA does not cause
26 pancreatic cancer at a higher rate than any other therapeutic agents for the
27 treatment of type 2 diabetes;
28

- 1 e. That BYETTA, JANUVIA, JANUMET and/or VICTOZA does not cause
2 death at a higher rate than any other therapeutic agents for the treatment
3 of type 2 diabetes; and
4 f. That BYETTA, JANUVIA, JANUMET and/or VICTOZA does not cause
5 any other severe personal injuries at a higher rate than any other
6 therapeutic agents for the treatment of type 2 diabetes.

7 As to each such test, attach copies of all test results and indicate whether they were ever
8 published and/or submitted to the FDA.

9 **Response to Interrogatory No. 19:**

10 NNI incorporates, as if fully set forth herein, the General Objections by reference.
11 NNI objects to this interrogatory as overly broad and unduly burdensome. NNI further
12 objects to this interrogatory to the extent it requests publicly available information. NNI
13 further objects to this interrogatory to the extent it requests NNI to review studies that
14 Plaintiffs can review themselves. NNI further objects to this interrogatory to the extent it
15 request information duplicative of a 30(b)(6) request served on NNI in this litigation.
16 NNI further objects to the extent that this interrogatory relates to or seeks information
17 regarding products other than Victoza®.

18 Subject to and without waiving the foregoing objections, NNI states that it will
19 produce charts identifying its completed and ongoing non-clinical and clinical studies for
20 Victoza® that were conducted by NNI that have been identified at this time. NNI further
21 states it will produce protocols and final study reports, to the extent available, for its
22 completed and ongoing non-clinical and clinical studies for Victoza® that were
23 conducted by NNI that have been identified at this time. NNI further states that it will
24 produce data sets, to the extent available, for its completed and ongoing clinical studies
25 for Victoza® that were conducted by NNI that have been identified at this time. NNI
26 further refers Plaintiffs to NNI's submissions and communications with the FDA,
27 produced at Bates ranges NNI-IND-61040-00000001 – NNI-IND-61040-00059607 and
28 NNI-NDA-22341-00000001 – NNI-NDA-22341-01380778. NNI further states that it will

1 meet and confer over the production of additional responsive data and information if
2 needed regarding, among other things, the appropriate scope and context of this request.
3

4 **Reason Why the Answer Should be Provided:**

5 The information requested in this interrogatory regarding incretin-based therapy
6 drugs is basic information in this case and should have been provided long ago. Instead,
7 defendant provides only a document dump of 59,607 + 1,380,778 pages. Plaintiffs do not
8 believe the “burden of deriving or ascertaining the answer will be substantially the same”
9 for them as for defendant, as required by Rule 33(d), if they have to read every page to
10 get the answers to this question and its subparts.

- 11 • Information about publication, lack of publication and the information requested in
12 a number of other subparts is important and may not be apparent from the test data
13 itself.
- 14 • If defendant has actually made all of the information requested in this interrogatory
15 publically available, it should state with precision where it is available.
- 16 • It is unclear from defendant’s objections whether it is attempting to limit its
17 response just to studies “conducted” by NNI, as opposed to all studies even if they
18 were conducted by others. All studies should be discoverable, not just those done
19 directly by NNI.
- 20 • Any science-related information defendant has on any incretin drugs should be
21 considered relevant in this matter, as it deals with the same general class of
22 medications. Defendant’s science-related work and/or comparative studies of
23 other incretin-based therapies can reasonably be expected to shed light on its own
24 drug.
- 25 • If defendant has already provided a complete answer to this question in the form of
26 a response to a 30(b)(6) request, it could have easily said so and pointed Plaintiffs
27 directly to that information. It did not. A responsive answer should be provided.
28

1
2 **Basis for Nondisclosure:**
3
4

5 **INTERROGATORY NO. 20:**

6 Please identify and describe all tests, investigations, studies, evaluations and/or
7 assessments conducted by YOU or on YOUR behalf, and/or relied upon by YOU either
8 in whole or in part, relating in any way to BYETTA, JANUVIA, JANUMET and/or
9 VICTOZA, including the following information:

- 10 a. If published, the exact title, author, publisher, place of publication, and
11 year of publication of any such test, investigation, study, evaluation
12 and/or assessment;
- 13 b. The dates that each such test, investigation, study, evaluation and/or
14 assessment was conducted;
- 15 c. The name and job title of each of YOUR employees, agents and/or
16 servants who were responsible for the performance and/or evaluation of,
17 and/or were in any way involved with the performance and/or evaluation
18 of, each such test, investigation, study, evaluation and/or assessment;
- 19 d. Whether the individuals identified in sub-paragraph (c) above are still
20 employed by YOU, and if not, their last known addresses and phone
21 numbers;
- 22 e. A step-by-step description of the methodology of each such test,
23 investigation, study, evaluation and/or assessment;
- 24 f. The purpose of each such test, investigation, study, evaluation and/or
25 assessment;
- 26 g. The full and complete verbatim results of each such test, investigation,
27 study, evaluation and/or assessment;
28

- 1 h. All raw data for each such test, investigation, study, evaluation and/or
- 2 assessment;
- 3 i. The date, manner, and means by which YOU first became aware of each
- 4 such test, investigation, study, evaluation and/or assessment; and
- 5 j. Whether such data was submitted to the FDA, and if so, on what date.

6

7 **Response to Interrogatory No. 20:**

8 NNI incorporates, as if fully set forth herein, the General Objections by reference.

9 NNI objects to this interrogatory as overly broad and unduly burdensome. NNI further

10 objects to this interrogatory to the extent it requests publicly available information. NNI

11 further objects to this interrogatory to the extent it requests NNI to review studies that

12 Plaintiffs can review themselves. NNI further objects to this interrogatory to the extent it

13 request information duplicative of a 30(b)(6) request served on NNI in this litigation.

14 NNI further objects to the extent that this interrogatory relates to or seeks information

15 regarding products other than Victoza®.

16 Subject to and without waiving the foregoing objections, NNI states that it will

17 produce charts identifying its completed and ongoing non-clinical and clinical studies for

18 Victoza® that were conducted by NNI that have been identified at this time. NNI further

19 states it will produce protocols and final study reports, to the extent available, for its

20 completed and ongoing non-clinical and clinical studies for Victoza® that were

21 conducted by NNI that have been identified at this time. NNI further states that it will

22 produce data sets, to the extent available, for its completed and ongoing clinical studies

23 for Victoza® that were conducted by NNI that have been identified at this time. NNI

24 further refers Plaintiffs to NNI's submissions and communications with the FDA,

25 produced at Bates ranges NNI-IND-61040-00000001 – NNI-IND-61040-00059607 and

26 NNI-NDA-22341-00000001 – NNI-NDA-22341-01380778. NNI further states that it will

27 meet and confer over the production of additional responsive data and information if

28 needed regarding, among other things, the appropriate scope and context of this request.

1
2 **Reason Why the Answer Should be Provided:**

3 The information requested in this interrogatory regarding incretin-based therapy
4 drugs is basic information in this case and should have been provided long ago. Instead,
5 defendant provides only a document dump of 59,607 + 1,380,778 pages. Plaintiffs do not
6 believe the “burden of deriving or ascertaining the answer will be substantially the same”
7 for them as for defendant, as required by Rule 33(d), if they have to read every page to
8 get the answers to this question and its subparts.

- 9
- 10 • Information about publication, lack of publication and the information requested in
11 a number of other subparts is important and may not be apparent from the test data
12 itself.
 - 13 • If defendant has actually made all of the information requested in this interrogatory
14 publically available, it should state with precision where it is available.
 - 15 • It is unclear from defendant’s objections whether it is attempting to limit its
16 response just to studies “conducted” by NNI, as opposed to all studies even if they
17 were conducted by others. All studies should be discoverable, not just those done
18 directly by NNI.
 - 19 • Any science-related information defendant has on any incretin drugs should be
20 considered relevant in this matter, as it deals with the same general class of
21 medications. Defendant’s science-related work and/or comparative studies of
22 other incretin-based therapies can reasonably be expected to shed light on its own
23 drug.
 - 24 • If defendant has already provided a complete answer to this question in the form of
25 a response to a 30(b)(6) request, it could have easily said so and pointed Plaintiffs
26 directly to that information. It did not. A responsive answer should be provided.
27

28 **Basis for Nondisclosure:**

1
2
3 **INTERROGATORY NO. 21:**

4 Identify any third parties utilized by YOU in the regulatory process either pre-launch or
5 post-launch, whether in the United States regulatory process or the regulatory process in
6 any other country (identifying each such country). Provide copies of any contracts,
7 agreement, or communications between YOU and any such third party.

8 **Response to Interrogatory No. 21:**

9 NNI incorporates, as if fully set forth herein, the General Objections by reference.
10 NNI further objects to this interrogatory as vague, ambiguous, and overly broad as it fails
11 to define certain terms and phrases, including “utilized” and “regulatory process.” NNI
12 objects further to this interrogatory to the extent it seeks information about regulatory
13 activities outside of the United States because it is neither relevant nor reasonably
14 calculated to lead to the discovery of admissible evidence, and is unduly burdensome to
15 produce in this litigation. NNI objects further to the extent this interrogatory seeks third-
16 party private, confidential, proprietary, or competitively sensitive or trade secret
17 information.

18 Subject to and without waiving or otherwise limiting the foregoing general and
19 specific objections, and pursuant to the parties’ agreement on February 3, 2014, NNI will
20 answer this interrogatory more fully at a later time, as needed, once its discovery and
21 document production are more substantially completed and upon mutual agreement by
22 the parties regarding, among other things, the appropriate scope and context of this
23 request.

24
25 **Reason Why the Answer Should be Provided:**

26 Third parties used in the regulatory process are sources of discoverable information
27 on science and general causation issues. Defendant relies on foreign studies and
28 activities (including EMA), and cannot shield itself from foreign discovery. The relevant

1 issues for general causation are the same here and abroad. Foreign discovery on matters
2 of global scope and importance is proper.

3
4 **Basis for Nondisclosure:**

5
6 **INTERROGATORY NO. 22:**

7 Did YOU or YOUR VICTOZA advisory board ever send or receive any oral or
8 written correspondence with the FDA and/or have any communication with the FDA,
9 whether in person, telephonic, or otherwise, concerning VICTOZA? If yes, then identify
10 and describe fully (a) all of the correspondence and/or communications; and (b) the date
11 all correspondence was sent and/or received by YOU and/or the date when the
12 communications occurred. Attach copies of all such correspondence and any recordings
13 (written or otherwise) of such communications. If the correspondence exists in electronic
14 format, produce it in its native electronic format.

15
16 **Response to Interrogatory No. 22:**

17 NNI incorporates, as if fully set forth herein, the General Objections by reference.
18 NNI further objects to this interrogatory as vague and ambiguous as it fails to define
19 certain terms, such as “advisory board.” NNI further objects to the extent this
20 interrogatory seeks “all of the correspondence and/or communications” as overly broad
21 and unduly burdensome.

22 Subject to and without waiving or otherwise limiting the foregoing general and
23 specific objections, NNI refers Plaintiffs to NNI’s submissions and communications with
24 the FDA, produced at Bates ranges NNI-IND-61040-00000001 – NNI-IND-61040-
25 00059607 and NNI-NDA-22341-00000001 – NNI-NDA-22341-01380778.

26
27 **Reason Why the Answer Should be Provided:**

1 Communications with the FDA by the defendant and those serving on its advisory
2 board for the medication at issue may be crucial to science issues. Such information is
3 routinely subject to discovery, but defendant provides only a document dump of 59,607 +
4 1,380,778 pages. Plaintiffs do not believe the “burden of deriving or ascertaining the
5 answer will be substantially the same” for them as for defendant, as required by Rule
6 33(d), if they have to read every page to get the answer to this question. Plaintiffs
7 respectfully submit that the term “advisory board” – as with the other common terms
8 defendant objects to as vague throughout its responses – is reasonably clear. A
9 responsive answer is needed.
10

11 **Basis for Nondisclosure:**

12
13 **INTERROGATORY NO. 23:**

14 Did the FDA or any advisory committee or sub-committee of the FDA or any other
15 governmental body ever hold any hearings as to the safety and/or efficacy of BYETTA,
16 JANUVIA, JANUMET and/or VICTOZA? If yes, identify the date(s), time(s), place(s),
17 and participants in the hearings; state whether YOU or anyone acting on YOUR behalf
18 provided testimony at any such hearings (including but not limited to hearings by the
19 FDA, CDC, NIH, USDA, U.S. Congress, and/or U.S. Senate); state the outcome of the
20 hearings; attach all transcripts of such hearings in native electronic form; and state
21 whether the FDA and/or any other governmental body ever suggested, requested, or
22 required YOU to provide further information and/or perform further tests as to the safety
23 of BYETTA, JANUVIA, JANUMET and/or VICTOZA.

24 **Response to Interrogatory No. 23:**

25 NNI incorporates, as if fully set forth herein, the General Objections by reference.
26 NNI further objects to this interrogatory as vague and ambiguous as it fails to define
27 certain terms, such as “advisory board.” NNI further objects to the extent this
28 interrogatory calls for information either not within NNI’s possession, custody, or control

1 and/or information that is a matter of public record or otherwise as accessible to Plaintiffs
2 as to NNI. NNI objects further to this interrogatory to the extent it seeks information
3 about regulatory processes and activities outside of the United States because it is neither
4 relevant nor reasonably calculated to lead to the discovery of admissible evidence, and is
5 unduly burdensome to produce in this litigation. NNI further objects to the extent that this
6 interrogatory relates to or seeks information regarding products other than Victoza®.

7 Subject to and without waiving or otherwise limiting the foregoing general and
8 specific objections, and pursuant to the parties' agreement on February 3, 2014, NNI will
9 answer this interrogatory more fully at a later time, as needed, once its discovery and
10 document production are more substantially completed and upon mutual agreement by
11 the parties regarding, among other things, the appropriate scope and context of this
12 request.

13 **Reason Why the Answer Should be Provided:**

14 Government hearings on safety issues are highly likely to include reference to the
15 science behind the medication, and whether it may be causing harm to consumers. Such
16 hearings, the presentations made, the outcomes, etc., are clearly relevant and should be
17 provided. Defendant relies on foreign studies and activities (including EMA), and cannot
18 shield itself from foreign discovery. The relevant issues on science and general causation
19 are the same here and abroad. The objection to other drugs is meritless, since any
20 science-related information defendant has on any incretin medication is relevant to the
21 same general class of medications.

22
23 **Basis for Nondisclosure:**

24
25 **INTERROGATORY NO 24:**

26 Identify all governmental agencies in all countries worldwide that declined to
27 approve, challenged, asked for additional study, or sought additional warnings before
28

1 approving YOUR application to market VICTOZA for any indication. Include in your
2 answer:

- 3 a. The country and agency;
- 4 b. The date approval was sought;
- 5 c. The date approval was denied, challenged, declined, or additional study
6 or warnings were sought;
- 7 d. The indication involved;
- 8 e. The reason for denial, challenge, decline, or seeking additional study or
9 warnings regarding the application;
- 10 f. The specifics of any additional study requested; and
- 11 g. The specifics of any additional warnings requested.

12 **Response to Interrogatory No. 24:**

13 NNI incorporates, as if fully set forth herein, the General Objections by reference.
14 NNI further to this interrogatory to the extent it seeks information about the regulatory
15 process outside of the United States because it is neither relevant nor reasonably
16 calculated to lead to the discovery of admissible evidence, and is unduly burdensome to
17 produce in this litigation.

18 Subject to and without waiving or otherwise limiting the foregoing general and
19 specific objections, NNI states that no regulatory body within the U.S. has denied
20 approval of Victoza®. NNI further refer Plaintiffs to NNI's submissions and
21 communications with the FDA, produced at Bates ranges NNI-IND-61040-00000001–
22 NNI-IND-61040-00059607 and NNI-NDA-22341-00000001 – NNI-NDA-22341-
23 01380778.

24 **Reason Why the Answer Should be Provided:**

25 The information requested in this interrogatory regarding approvals, challenges,
26 requests for additional studies or warnings, etc. is basic information in this case and
27 should have been provided long ago. Instead, defendant provides only a document dump
28 of 59,607 + 1,380,778 pages. Plaintiffs do not believe the “burden of deriving or

1 ascertaining the answer will be substantially the same” for them as for defendant, as
2 required by Rule 33(d), if they have to read every page to get the answers to this question
3 and its subparts. Defendant relies on foreign studies and activities (including EMA), and
4 cannot shield itself from foreign discovery. The relevant issues on science and general
5 causation are the same here and abroad.

6
7 **Basis for Nondisclosure:**

8
9
10 **INTERROGATORY NO. 29:**

11 Identify all advertising, promotional, marketing, sales and/or public relations
12 efforts or campaigns directed to health care providers planned and/or implemented by
13 YOU or others on YOUR behalf concerning VICTOZA, whether in writing or
14 communicated by any other media and/or medium. For all such advertising, promotional,
15 marketing, sales and/or public relations efforts or campaigns directed to health care
16 providers, please identify:

- 17 a. The names and addresses of all persons and/or entities responsible for all
18 such advertising, promotional, marketing, sales and/or public relations
19 efforts or campaigns;
- 20 b. The dates that such advertising, promotional, marketing, sales and/or
21 public relations efforts or campaigns were conducted;
- 22 c. The specific media vehicles by which the advertising, promotional,
23 marketing, sales and/or public relations efforts or campaigns were
24 conducted (i.e., print, television, radio, outdoor, etc.);
- 25 d. All documents pertaining to the development of marketing strategies or
26 programs for the sale and/or distribution of VICTOZA;
- 27 e. All documents pertaining to the implementation of marketing strategies
28 or marketing programs in connection with VICTOZA;

- f. All documents describing all marketing strategies and/or programs concerning VICTOZA;
- g. All documents pertaining to the intended “market” for VICTOZA, including documents pertaining to sales targets, distribution and/or survey data;
- h. All drafts of any advertising and/or promotional literature concerning VICTOZA;
- i. All documents reflecting pricing for VICTOZA;
- j. All documents pertaining to sums of money that YOU budgeted in order to advertise, promote and/or market VICTOZA;
- k. All press releases prepared in connection with VICTOZA; and
- l. All press kits prepared in connection with VICTOZA.

Response to Interrogatory No. 29:

NNI incorporates, as if fully set forth herein, the General Objections by reference. NNI further objects to this interrogatory as vague and ambiguous as it fails to define certain terms, such as “media vehicles.” NNI further objects to this interrogatory to the extent it seeks information regarding NNI’s advertising, promotional, marketing, sales and/or public relations efforts outside the United States, including those directed to health care providers. NNI further objects to this interrogatory because it is overly broad and unduly burdensome.

Reason Why the Answer Should be Provided:

Advertising and marketing directed to healthcare professionals (as opposed to consumers) can be expected to refer to and attempt to explain the science behind the medication. Plaintiffs have suspended their requests for this type of information as directed to *non-professionals* because it is not likely to inform the discussion of scientific and general causation issues. The information requested here, however, is relevant to

1 those issues and should be provided in accordance with Judge Battaglia’s admonition that
2 information is to be assessed on its merits, as opposed to whether it is placed in a
3 marketing category or any other category not specifically labeled as science. And again,
4 Defendant relies on foreign studies and activities (including EMA), and cannot shield
5 itself from foreign discovery. The relevant issues on science and general causation are
6 the same here and abroad.

7
8 **Basis for Nondisclosure:**

9
10
11 **INTERROGATORY NO. 31:**

12 Identify all conferences and/or events sponsored by YOU where VICTOZA was
13 referred to, including in your response the title, date and location of the conferences
14 and/or events; a description of the materials provided at each conference and/or event,
15 including but not limited to any brochures for the conferences and/or events; and describe
16 any agenda for each such conference and/or event.

17 **Response to Interrogatory No. 31:**

18 NNI incorporates, as if fully set forth herein, the General Objections by reference.
19 NNI further objects to this interrogatory as vague and ambiguous as it fails to define
20 certain terms and phrases, such as “events,” “sponsored,” and “referred to.” NNI further
21 objects to this interrogatory to the extent it is overly broad and unduly burdensome.

22
23 **Reason Why the Answer Should be Provided:**

24 Conferences and events sponsored by a drug manufacturer for a drug are one of the
25 common methods by which the science behind the drug is presented and/or explained.
26 Plaintiffs are entitled to that information as they prepare their case on the science and
27 general causation issues pertaining to the incretin medications. Plaintiffs respectfully
28 submit that the terms “events” and “sponsored” and “referred to” – as with the other

1 common terms defendant objects to as vague throughout its responses – are reasonably
2 clear. A responsive answer is needed.

3
4 **Basis for Nondisclosure:**

5
6 **INTERROGATORY NO. 32:**

7 Did the FDA or any advisory committee or sub-committee of the FDA or any other
8 governmental body ever request that YOU cease dissemination of promotional materials
9 for VICTOZA for any of the following reasons:

- 10 a. Broadening of the VICTOZA indication;
11 b. Overstating the efficacy of VICTOZA;
12 c. Minimizing serious risks associated with the use of VICTOZA; or
13 d. Any other reasons not included in a-c.

14 If so, identify any and all ways in which the promotional materials were deemed to be
15 misleading; and identify any and all submissions, corrections and/or plans of action to
16 correct the misleading promotional materials.

17 **Response to Interrogatory No. 32:**

18 NNI incorporates, as if fully set forth herein, the General Objections by reference.
19 NNI further objects to this interrogatory to the extent it seeks information about
20 regulatory activities outside the United States because it is neither relevant nor reasonably
21 calculated to lead to the discovery of admissible evidence and is unduly burdensome.

22 Subject to and without waiving or otherwise limiting the foregoing general and
23 specific objections, NNI refers Plaintiffs to NNI's submissions and communications with
24 the FDA, produced at Bates ranges NNI-IND-61040-00000001 – NNI-IND-61040-
25 00059607 and NNI-NDA-22341-00000001 – NNI-NDA-22341-01380778.

26
27 **Reason Why the Answer Should be Provided:**

1 The information requested in this interrogatory regarding governmental action
2 taken with respect to misleading promotional materials is basic information in this case
3 and should have been provided long ago. Instead, defendant provides only a document
4 dump of 59,607 + 1,380,778 pages. Plaintiffs do not believe the “burden of deriving or
5 ascertaining the answer will be substantially the same” for them as for defendant, as
6 required by Rule 33(d), if they have to read every page to get the answers to this question
7 and its subparts. Again, Defendant relies on foreign studies and activities (including
8 EMA), and cannot shield itself from foreign discovery. The relevant issues on science
9 and general causation are the same here and abroad.
10

11 **Basis for Nondisclosure:**

12
13 **INTERROGATORY NO. 33:**

14 Identify all reports of adverse reactions, injuries, and/or ADVERSE EVENTS in
15 humans that YOU ever became aware from any source, including but not limited to the
16 medical community, the press, and/or peer reviewed medical and/or scientific articles,
17 domestic or international, with respect to exenatide, sitagliptin, liraglutide and/or any
18 other GLP-1 agonist or DPP-4 inhibitor. As to each report, if published, identify the
19 author(s), date of publication, place(s) of publications, and title; and identify YOUR
20 action(s), if any, with respect to the continued sales, distribution, and/or marketing of an
21 exenatide, sitagliptin, liraglutide, and/or any other GLP-1 agonist or DPP-4 inhibitor-
22 containing diabetes medication upon learning of each report. Provide copies of all such
23 reports, and if these reports exist in electronic format, please produce them in their native
24 electronic format.

25 **Response to Interrogatory No. 33:**

26 NNI incorporates, as if fully set forth herein, the General Objections by reference.
27 NNI further objects to this interrogatory insofar as vague, overly broad, and unduly
28 burdensome. NNI further objects to this interrogatory to the extent it seeks information

1 concerning products other than Victoza®. NNI further objects to this interrogatory to the
2 extent it requests information not related to the injuries at issue in this litigation. NNI
3 further objects to this interrogatory to the extent it seeks information from sources outside
4 the United States because it is neither relevant nor reasonably calculated to lead to the
5 discovery of admissible evidence and is unduly burdensome.

6 Subject to and without waiving the foregoing objections, NNI will meet and confer
7 with Plaintiffs over a production of its Victoza® adverse event files relating to the
8 injuries at issue in the litigation and refers Plaintiffs to the information contained therein.

9 **Reason Why the Answer Should be Provided:**

10 Obtaining complete and accurate information about adverse event reports on
11 pancreatitis and pancreatic cancer is crucial. This information is relied upon for signal
12 detection and it drives decision-making on medication science, study design and related
13 matters. This applies across all of the incretin medications, so if defendant has adverse
14 event reports for any medications other than its own, those should be provided as well. If
15 it does not have adverse event reports for other medications, it can easily state as much.
16 As to foreign discovery on this issue, there is nothing to distinguish pancreatitis or
17 pancreatic cancer in foreign countries from the same conditions in the U.S. Defendant
18 relies on foreign studies and activities (including EMA), and cannot shield itself from
19 foreign discovery. The relevant issues on science and general causation are the same
20 here and abroad.

21
22 **Basis for Nondisclosure:**

23
24 **INTERROGATORY NO. 34:**

25 Beginning with the time when YOU first began to design, develop, manufacture,
26 market, distribute, and/or sell VICTOZA, up through and including the present, was
27 VICTOZA ever listed in the Physicians' Desk Reference ("PDR")? If so, please state
28 whether YOU or others on YOUR behalf indicated a use for VICTOZA in the PDR or in

1 any other source and, if so, describe with particularity the information provided by YOU
2 or others on YOUR behalf to the PDR, including but not limited to all correspondence,
3 cover letters, attachments and other documents, as well as all information actually
4 published in the PDR.

5 **Response to Interrogatory No. 34:**

6 NNI incorporates, as if fully set forth herein, the General Objections by reference.
7 NNI further objects to this interrogatory insofar as the information sought is a matter of
8 public record or otherwise as accessible to Plaintiffs as to NNI.

9 Subject to and without waiving the foregoing objections, NNI states that Victoza®
10 has been listed in the PDR, either in print or online, since 2010.

11
12 **Reason Why the Answer Should be Provided:**

13 This question asks for the information defendant *provided* to the PDR, which is
14 reasonably likely to be heavily science-oriented and is not, to Plaintiffs' knowledge,
15 available in the public domain. The information actually published in the PDR is
16 otherwise available to Plaintiffs and need not be provided.

17
18 **Basis for Nondisclosure:**

19
20 **INTERROGATORY NO. 35:**

21 During the period when YOU first began to develop, design, manufacture, market,
22 distribute and/or sell VICTOZA, up through the present, please state the following as to
23 the VICTOZA package insert:

- 24 a. The indications for use during each year;
25 b. The contraindications each year;
26 c. The warnings each year;
27 d. The adverse reactions each year; and,
28 e. The dosage amounts each year.

1 Identify any and all changes made during this time period in each of the above categories,
2 stating the date when each change was made, why each change was made, and who
3 ordered each change. Please also state, if and when any changes were made, whether
4 there were any drafts and/or other proposals prior to the final and/or ultimate change. If
5 YOUR answer is in the affirmative, please identify each draft and/or proposal and
6 provide copies of same. If each draft and/or proposal exists in electronic format, please
7 produce them in their native electronic format.

8 **Response to Interrogatory No. 35:**

9 NNI incorporates, as if fully set forth herein, the General Objections by reference.
10 NNI further objects to the extent this interrogatory requests information related to the
11 development, design, manufacture, marketing and/or sale of Victoza® outside the United
12 States. NNI further objects to this interrogatory to the extent that the information
13 requested is publicly available to Plaintiffs.

14 Subject to and without waiving or otherwise limiting the foregoing objections, NNI
15 refers Plaintiffs to NNI refers Plaintiffs to NNI's submissions and communications with
16 the FDA, produced at Bates ranges NNI-IND-61040-00000001– NNI-IND-61040-
17 00059607 and NNI-NDA-22341-00000001 – NNI-NDA-22341- 01380778. NNI further
18 states that it will make a separate production of Victoza® package inserts and refers
19 Plaintiffs to the information contained therein.

20
21 **Reason Why the Answer Should be Provided:**

22 The information requested in this interrogatory regarding the package insert is
23 basic information in this case and should have been provided long ago. Instead,
24 defendant provides only a document dump of 59,607 + 1,380,778 pages. Plaintiffs do not
25 believe the “burden of deriving or ascertaining the answer will be substantially the same”
26 for them as for defendant, as required by Rule 33(d), if they have to read every page to
27 get the answers to this question and its subparts. Again, Defendant relies on foreign
28

1 studies and activities (including EMA), and cannot shield itself from foreign discovery.
2 The relevant issues on science and general causation are the same here and abroad.
3
4

5 **Basis for Nondisclosure:**
6

7 **INTERROGATORY NO. 36:**

8 Identify all medical literature, including articles, studies, editorials, and/or any peer
9 reviewed material in YOUR possession that mentions, identifies or sets forth any
10 elevated hazards, risks, side effects, adverse reactions and/or dangers from the use of
11 BYETTA, JANUVIA, JANUMET and/or VICTOZA, and with respect to each, please
12 identify the date, manner, and means by which YOU first became aware of same.

13 **Response to Interrogatory No. 36:**

14 NNI incorporates, as if fully set forth herein, the General Objections by reference.
15 NNI further objects to this interrogatory insofar as the information sought is a matter of
16 public record or otherwise as accessible to Plaintiffs as to NNI. NNI further objects to
17 this interrogatory because it is overly broad and unduly burdensome.
18

19 **Reason Why the Answer Should be Provided:**

20 This interrogatory seeks information about the medical literature defendant has,
21 and while the literature itself may (or may not) be publicly available, to the best of
22 Plaintiffs' knowledge there is no public posting of the literature in defendant's
23 possession. If there is one, defendant should direct Plaintiffs to it. The medical and
24 scientific literature on the incretin medications goes to the heart of this case. It should be
25 clearly identified. A responsive answer should be provided.
26

27 **Basis for Nondisclosure:**
28

1 **INTERROGATORY NO. 37:**

2 State whether VICTOZA subjected users to any adverse effects and/or side effects
3 that a user of VICTOZA may experience at a higher rate than they would as a user of any
4 other therapeutic agents for the treatment of type 2 diabetes. If YOUR answer is in the
5 affirmative, please describe any and all adverse effects and/or side effects that a user of
6 VICTOZA may experience from the use of VICTOZA at a higher rate than as a user of
7 any other therapeutic agents for the treatment of type 2 diabetes. Please also identify the
8 means by which these adverse effects and/or side effects and the rate at which they are
9 likely to occur are made known to the patient and/or user of VICTOZA, whether by any
10 writing, instructional video, package insert, poster, letter, and/or any other means. Please
11 also provide copies of all the writing(s), instructional video(s), package insert(s),
12 poster(s), letter(s), and/or any other means referred to above, including copies of any and
13 all change(s), drafts, revision(s), and/or modification(s) made to same.

14 **Response to Interrogatory No. 37:**

15 NNI incorporates, as if fully set forth herein, the General Objections by reference.
16 NNI further objects to this interrogatory to the extent it seeks information unrelated to the
17 alleged risks and injuries at issue in this litigation. NNI further objects to this
18 interrogatory to the extent it seeks information concerning activities outside the United
19 States including the occurrence of adverse events or side effects. NNI further objects to
20 this interrogatory to the extent it calls for expert opinion or testimony.

21
22 **Reason Why the Answer Should be Provided:**

23 Defendant should be required to clarify its response to this interrogatory. If it does
24 not know the answer to the question independently of securing expert assistance, it
25 should be required to say so. In that event, Plaintiffs would agree to await expert
26 discovery before expecting an answer to the question. However, if defendant has
27 information responsive to the interrogatory independent of information it may obtain
28 from experts, that information should be provided. Many of the subjects at issue in this

1 litigation and in these interrogatories will be subject to expert testimony. That does not
2 mean responsive information that exists independently of expert testimony can be
3 shielded from discovery until expert disclosures are due. Again, Defendant relies on
4 foreign studies and activities (including EMA), and cannot shield itself from foreign
5 discovery. The relevant issues on science and general causation are the same here and
6 abroad.

7
8 **Basis for Nondisclosure:**

9
10 **INTERROGATORY NO. 38:**

11 State whether YOU have ever received any complaint(s), domestic or international,
12 of any of the following adverse events: (a) cancer; (b) pancreatic cancer; (c) pancreatitis;
13 and (d) death, from any consumer, VICTOZA user, doctors, physicians and/or healthcare
14 professionals concerning VICTOZA, beginning in the year YOU first started developing,
15 designing, manufacturing, marketing, distributing, promoting, and/or selling VICTOZA,
16 up through and including the present. If YOUR answer is in the affirmative, then identify
17 and explain the process by which YOU receive complaints regarding VICTOZA from
18 consumers, as well as doctors, physicians and/or healthcare professionals. Please also
19 state the total number of complaints YOU have received for each type of complaint, (a)
20 through (d), from consumers, doctors, physicians and/or healthcare professionals
21 concerning VICTOZA, and state the number of each type of complaint, (a) through (d),
22 by year. Please provide copies of all such complaints or reports of complaints. If the
23 complaints or reports of complaints exist in electronic format, produce them in their
24 native electronic format.

25 **Response to Interrogatory No. 38:**

26 NNI incorporates, as if fully set forth herein, the General Objections by reference.
27 NNI further objects to this interrogatory as vague and ambiguous. NNI further objects to
28 the extent this interrogatory seeks case-specific information. NNI further objects to this

1 interrogatory to the extent it seeks information unrelated to the alleged risks and injuries
2 at issue in this litigation. NNI further objects to this interrogatory to the extent “cancer” is
3 an overly broad, vague and ambiguous terms and relates to injuries not at issue in the
4 litigation. NNI further objects to this interrogatory to the extent it seeks information
5 concerning activities outside the United States because it is neither relevant nor
6 reasonably calculated to lead to the discovery of admissible evidence and is unduly
7 burdensome.

8 Subject to and without waiving the foregoing objections, NNI will meet and confer
9 with Plaintiffs regarding a production of its Victoza® adverse event files relating to the
10 injuries at issue in the litigation and refers Plaintiffs to the information contained therein.
11

12 **Reason Why the Answer Should be Provided:**

13 Obtaining complete and accurate information about adverse event reports on
14 pancreatitis and pancreatic cancer is crucial. This information is relied upon for signal
15 detection and it drives decision-making on medication science, study design and related
16 matters. As to foreign discovery on this issue, there is nothing to distinguish pancreatitis
17 or pancreatic cancer in foreign countries from the same conditions in the U.S. Defendant
18 relies on foreign studies and activities (including EMA), and cannot shield itself from
19 foreign discovery. The relevant issues on science and general causation are the same
20 here and abroad. The requested information should be provided.
21

22 **Basis for Nondisclosure:**

23
24 **INTERROGATORY NO. 39:**

25 Identify each person acting on YOUR behalf who has been responsible for: (a)
26 receiving any complaints, inquiries, letters and other documents pertaining to VICTOZA;
27 (b) evaluating any complaints, inquiries, letters, and other documents pertaining to
28 VICTOZA; (c) investigating any complaints, inquiries, letters or other documents

1 pertaining to VICTOZA; and (d) responding to any complaints, inquiries, letters and
2 other documents pertaining to VICTOZA.

3 **Response to Interrogatory No. 39:**

4 NNI incorporates, as if fully set forth herein, the General Objections by reference.
5 NNI further objects to this interrogatory as vague and ambiguous as it fails to define
6 certain terms and phrases, including “on your behalf,” “responsible,” “inquiries,”
7 “complaints” and “responding.” NNI further objects to this interrogatory to the extent it
8 seeks information unrelated to the alleged risks and injuries at issue in this litigation. NNI
9 further objects to this interrogatory to the extent it seeks information concerning activities
10 outside the United States because it is neither relevant nor reasonably calculated to lead
11 to the discovery of admissible evidence and is unduly burdensome.

12 Subject to and without waiving or otherwise limiting the foregoing general and
13 specific objections, and pursuant to the parties’ agreement on February 3, 2014, NNI will
14 answer this interrogatory more fully at a later time, as needed, once its discovery and
15 document production are more substantially completed and upon mutual agreement by
16 the parties regarding, among other things, the appropriate scope and context of this
17 request.

18
19 **Reason Why the Answer Should be Provided:**

20 Obtaining complete and accurate information about adverse event reports on
21 pancreatitis and pancreatic cancer is crucial. This information is relied upon for signal
22 detection and it drives decision-making on medication science, study design and related
23 matters. The people who should be identified in response to this interrogatory will be
24 potential sources of discoverable information. As to foreign discovery on this issue, there
25 is nothing to distinguish pancreatitis or pancreatic cancer in foreign countries from the
26 same conditions in the U.S. Defendant relies on foreign studies and activities (including
27 EMA), and cannot shield itself from foreign discovery. The relevant issues on science
28

1 and general causation are the same here and abroad. The requested information should
2 be provided.

3
4
5 **Basis for Nondisclosure:**

6
7 **INTERROGATORY NO. 40:**

8 Identify each of YOUR employees, independent contractors or other agents,
9 whether in the United States or abroad, who at any time expressed any concerns
10 regarding the safety of BYETTA, JANUVIA, JANUMET and/or VICTOZA, including,
11 without limitation, concerns about the risks of cancers, including but not limited to
12 pancreatic cancer, pancreatitis, and/or death from the use of BYETTA, JANUVIA,
13 JANUMET and/or VICTOZA. Include in your response any concerns expressed about
14 matters before the FDA, or matters that arose during clinical studies, testing, or post-
15 market surveillance. With respect to each matter for which concerns were expressed
16 regarding the safety of BYETTA, JANUVIA, JANUMET and/or VICTOZA as described
17 above, state the substance of the concerns expressed by each person identified; identify
18 all documents that state or discuss such concerns; and describe in detail what action, if
19 any, YOU took in response to those concerns.

20 **Response to Interrogatory No. 40:**

21 NNI incorporates, as if fully set forth herein, the General Objections by reference.
22 NNI further objects to this interrogatory as it is overly broad, unduly burdensome, and
23 improperly seeks information beyond the scope of the Federal Rules of Civil Procedure.
24 NNI further objects to this interrogatory as vague, ambiguous, and overbroad as it fails to
25 define certain terms and phrases, including “independent contractors,” “expressed,” or
26 “concern.” NNI further objects to the extent that this interrogatory seeks a legal
27 conclusion. NNI further objects to this interrogatory to the extent it seeks information
28 unrelated to the alleged risks and injuries at issue in this litigation. NNI further objects to

1 this interrogatory to the extent it seeks information concerning products other than
2 Victoza®. NNI further objects to this interrogatory to the extent it seeks information
3 concerning activities outside the United States because it is neither relevant nor
4 reasonably calculated to lead to the discovery of admissible evidence and is unduly
5 burdensome.

6
7 **Reason Why the Answer Should be Provided:**

8 One of the key methods by which problems with medications are discovered and
9 resolved is when those working with the medication begin to ask questions and raise
10 concerns. There may or may not be dramatic revelations (i.e., someone expressing
11 concerns that data falsified or omitted from clinical studies may lead to the untimely
12 deaths of innocent people), but *any* concerns expressed about the risks of cancer and
13 pancreatitis are crucial to an understanding of the science and resolution of the general
14 causation issues (e.g., an employee querying whether another study should be done to
15 resolve an unsettled issue; or asking if a particular pancreatic cancer victim really ought
16 to have been excluded from the results of a clinical trial).

17 This applies across all of the incretin medications, so if defendant's employees,
18 contractors, etc. have expressed concerns about other medications, that information is
19 also relevant and should be provided. If defendant does not have such information for
20 other medications, it can easily state as much.

21 As to foreign discovery on this issue, there is nothing to distinguish concerns
22 expressed about pancreatitis or pancreatic cancer occurring in foreign countries, or
23 concerns expressed in foreign countries, from the same circumstances in the U.S.
24 Defendant relies on foreign studies and activities (including EMA), and cannot shield
25 itself from foreign discovery. The relevant issues on science and general causation are
26 the same here and abroad. The requested information should be provided.

27
28 **Basis for Nondisclosure:**

1
2
3
4 **INTERROGATORY NO. 41:**

5 State whether exenatide, sitagliptin, liraglutide and/or any other GLP-1 agonist or
6 DPP-4 inhibitor subjects users to any potential adverse effects and/or side effects. If
7 YOUR answer is in the affirmative, please describe any and all adverse effects and/or
8 side effects that a user of exenatide, sitagliptin, liraglutide and/or any other GLP-1
9 agonist or DPP-4 inhibitor could experience. Please also identify the means by which
10 those adverse effects and/or side effects are made known by YOU to the users of
11 exenatide, sitagliptin, liraglutide and/or any other GLP-1 agonist or DPP-4 inhibitor,
12 whether by any writing, instructional video, package insert, poster, letter, and/or any
13 other means. Please also provide copies of all writing(s), instructional video(s), package
14 insert(s), poster(s), letter(s), and/or any other means employed by YOU, including copies
15 of any and all change(s), drafts, revision(s), and/or modification(s) made to same.

16 **Response to Interrogatory No. 41:**

17 NNI incorporates, as if fully set forth herein, the General Objections by reference.
18 NNI further objects to this interrogatory as it is overly broad, unduly burdensome, and
19 improperly seeks information beyond the scope of the Federal Rules of Civil Procedure.
20 NNI further objects to this interrogatory to the extent it seeks information unrelated to the
21 alleged risks and injuries at issue in this litigation. NNI further objects to this
22 interrogatory to the extent it seeks information concerning products other than Victoza®.
23 NNI further objects to this interrogatory to the extent it seeks information concerning
24 activities outside the United States.

25 Subject to and without waiving or otherwise limiting the foregoing general and
26 specific objections, NNI directs Plaintiffs to NNI's submissions and communications
27 with the FDA, produced at Bates ranges NNI-IND-61040-00000001 – NNI-IND-61040-
28 00059607 and NNI-NDA-22341-00000001 – NNI-NDA-22341-01380778. NNI will

1 meet and confer with Plaintiffs regarding a production of its Victoza® adverse event files
2 relating to the injuries at issue in the litigation and refers Plaintiffs to the information
3 contained therein. NNI will make a production of its U.S. Victoza® package inserts and
4 refers Plaintiffs to the information contained therein.

5
6 **Reason Why the Answer Should be Provided:**

7 The information requested in this interrogatory regarding the side effects of the
8 incretin medications, and particularly those with respect to pancreatitis and pancreatic
9 cancer, is basic information in this case and should have been provided long ago.
10 Instead, defendant provides only a document dump of 59,607 + 1,380,778 pages.
11 Plaintiffs do not believe the “burden of deriving or ascertaining the answer will be
12 substantially the same” for them as for defendant, as required by Rule 33(d), if they have
13 to read every page to get the answers to this question and its subparts.

14 The issues of pancreatitis and pancreatic cancer apply across all of the incretin
15 medications, so if defendant has information about those side effects with other incretin
16 drugs, that information is also relevant and should be provided. If defendant does not
17 have such information for other medications, it can easily state as much.

18 Again, Defendant relies on foreign studies and activities (including EMA), and
19 cannot shield itself from foreign discovery. The relevant issues on science and general
20 causation are the same here and abroad.

21
22 **Basis for Nondisclosure:**

23
24 **INTERROGATORY NO. 42:**

25 State whether exenatide, sitagliptin, liraglutide and/or any other GLP-1 agonist or
26 DPP-4 inhibitor subjects users to any potential adverse effects and/or side effects at a
27 higher rate than they would experience as a user of a therapeutic agent for the treatment
28 of type 2 diabetes containing an active ingredient other than exenatide, sitagliptin,

1 liraglutide and/or any other GLP-1 agonist or DPP-4 inhibitor. If YOUR answer is in the
2 affirmative, please describe any and all adverse effects and/or side effects that a user of
3 exenatide, sitagliptin, liraglutide and/or any other GLP-1 agonist or DPP-4 inhibitor
4 would experience at a higher rate than they would experience as a user of a therapeutic
5 agent for the treatment of type 2 diabetes containing an active ingredient other than
6 exenatide, sitagliptin, liraglutide and/or any other GLP-1 agonist or DPP-4 inhibitor.
7 Please also identify the means by which the higher rates of those adverse effects and/or
8 side effects are made known by YOU to the users of exenatide, sitagliptin, liraglutide
9 and/or any other GLP-1 agonist or DPP-4 inhibitor, whether by any writing, instructional
10 video, package insert, poster, letter, and/or any other means. Please also provide copies
11 of all writing(s), instructional video(s), package insert(s), poster(s), letter(s), and/or any
12 other means employed by YOU, including copies of any and all change(s), drafts,
13 revision(s), and/or modification(s) made to same.

14 **Response to Interrogatory No. 42:**

15 NNI incorporates, as if fully set forth herein, the General Objections by reference.
16 NNI further objects to this interrogatory as it is overly broad, unduly burdensome, and
17 improperly seeks information beyond the scope of the Federal Rules of Civil Procedure.
18 NNI further objects to this interrogatory to the extent it seeks information unrelated to the
19 alleged risks and injuries at issue in this litigation. NNI further objects to this
20 interrogatory to the extent it seeks information concerning products other than Victoza®.
21 NNI further objects to this interrogatory to the extent it seeks information concerning
22 activities outside the United States. NNI further objects to this interrogatory to the extent
23 it calls for expert opinion or testimony.

24
25 **Reason Why the Answer Should be Provided:**

26 Defendant should be required to clarify its response to this interrogatory. If it does
27 not know the answer to the question independently of securing expert assistance, it
28 should be required to say so. In that event, Plaintiffs would agree to await expert

1 discovery before expecting an answer to the question. However, if defendant has
2 information responsive to the interrogatory independent of information it may obtain
3 from experts, that information should be provided. Many of the subjects at issue in this
4 litigation and in these interrogatories will be subject to expert testimony. That does not
5 mean responsive information that exists independently of expert testimony can be
6 shielded from discovery until expert disclosures are due. Again, Defendant relies on
7 foreign studies and activities (including EMA), and cannot shield itself from foreign
8 discovery. The relevant issues on science and general causation are the same here and
9 abroad.

10
11 **Basis for Nondisclosure:**

12
13
14 **INTERROGATORY NO. 43:**

15 Identify all instructions and/or warnings that accompanied VICTOZA and all
16 drafts of instructions and/or warnings regarding VICTOZA at any time that VICTOZA
17 was marketed or sold in any country. Please also:

- 18 a. Provide the content of any such instruction and/or warning and/or draft of
19 such instruction and/or warning;
20 b. State the manner each instruction and/or warning was attached to and/or
21 accompanied VICTOZA;
22 c. Identify the name(s) of the person(s) responsible for creating each such
23 instruction and/or warning and/or draft of such instruction and/or
24 warning, and state whether they are still employed by YOU, and if not,
25 then provide their last known addresses and phone numbers;
26 d. Identify the name(s) of the person(s) who approved each such instruction
27 and/or warning, and state whether they are still employed by YOU, and if
28 not, then provide their last known addresses and phone numbers; and

1 e. State the purpose of each such warning and instruction.

2 **Response to Interrogatory No. 43:**

3 NNI incorporates, as if fully set forth herein, the General Objections by reference.
4 NNI objects to this interrogatory as vague and ambiguous as it fails to define certain
5 terms and phrases, including “accompanied,” “content,” “attached,” and “approved.” NNI
6 further objects to the extent this interrogatory requests information related to Victoza®
7 activities outside the United States.

8 Subject to and without waiving or otherwise limiting the foregoing general and
9 specific objections, NNI directs Plaintiffs to NNI’s submissions and communications
10 with the FDA, produced at Bates ranges NNI-IND-61040-00000001 – NNI-IND-61040-
11 00059607 and NNI-NDA-22341-00000001 – NNI-NDA-22341-01380778. NNI will
12 make a production of its U.S. Victoza® package inserts and refers Plaintiffs to the
13 information contained therein.

14
15 **Reason Why the Answer Should be Provided:**

16 The information requested in this interrogatory regarding instructions and warnings
17 is basic information in this case and should have been provided long ago. Instead,
18 defendant provides only a document dump of 59,607 + 1,380,778 pages. Plaintiffs do not
19 believe the “burden of deriving or ascertaining the answer will be substantially the same”
20 for them as for defendant, as required by Rule 33(d), if they have to read every page to
21 get the answers to this question and its subparts.

22 Again, Defendant relies on foreign studies and activities (including EMA), and
23 cannot shield itself from foreign discovery. The relevant issues on science and general
24 causation are the same here and abroad.

25
26 **Basis for Nondisclosure:**

1
2
3 **INTERROGATORY NO. 44:**

4 State whether any changes, revisions and/or modifications were made to any
5 warning and/or instruction that accompanied VICTOZA at any time that VICTOZA was
6 marketed or sold in any country. If YOUR answer is in the affirmative, please:

- 7 a. Identify the change(s), revision(s) and/or modification(s);
8 b. State the date(s) of any change(s), revision(s), and/or modification(s);
9 c. State the reason for the change(s), revision(s), and/or modification(s);
10 and
11 d. Identify the name(s) of the person(s) who approved the change(s),
12 revision(s) and/or modification(s), and state whether they are still
13 employed by YOU, and if not, then provide their last known addresses
14 and phone numbers.

15 Please also attach copies of all documents pertaining to the changes, revisions and/or
16 modifications made to the instructions and/or warnings, as well as copies of all
17 communications (written or otherwise), both internal and/or with the FDA, concerning
18 any changes, revisions and/or modification concerning VICTOZA.

19 **Response to Interrogatory No. 44:**

20 NNI incorporates, as if fully set forth herein, the General Objections by reference.
21 NNI objects to this interrogatory as vague and ambiguous as it fails to define certain
22 terms and phrases, including “revisions,” and “modifications.” NNI further objects to the
23 extent this interrogatory requests information related to Victoza® activities outside the
24 United States.

25 Subject to and without waiving or otherwise limiting the foregoing general and
26 specific objections, NNI directs Plaintiffs to NNI’s submissions and communications
27 with the FDA, produced at Bates ranges NNI-IND-61040-00000001 – NNI-IND-61040-
28 00059607 and NNI-NDA-22341-00000001 – NNI-NDA-22341-01380778. NNI will

1 make a production of its U.S. Victoza® package inserts and refers Plaintiffs to the
2 information contained therein.

3 **Reason Why the Answer Should be Provided:**

4 The information requested in this interrogatory regarding changes to instructions
5 and warnings is basic information in this case and should have been provided long ago.
6 Instead, defendant provides only a document dump of 59,607 + 1,380,778 pages.
7 Plaintiffs do not believe the “burden of deriving or ascertaining the answer will be
8 substantially the same” for them as for defendant, as required by Rule 33(d), if they have
9 to read every page to get the answers to this question and its subparts.

10 Again, Defendant relies on foreign studies and activities (including EMA), and
11 cannot shield itself from foreign discovery. The relevant issues on science and general
12 causation are the same here and abroad.

13
14 **Basis for Nondisclosure:**

15
16
17 **INTERROGATORY NO. 45:**

18 Have YOU ever issued a warning letter and/or “Dear Doctor” and/or “Dear
19 healthcare provider” letter to the medical community either in the United States or in any
20 other country regarding VICTOZA? If YOUR answer is in the affirmative, please state:

- 21 a. Who first suggested sending such letter;
22 b. Who composed each letter;
23 c. The date of each letter;
24 d. To whom the letter was sent;
25 e. How the identities and addresses of the recipients of each letter were
26 determined; and
27 f. Whether subsequent letter(s) were sent and, if so, please identify:
28 1. Who suggested sending the subsequent letter(s);

- 1 2. Who composed the letter(s);
- 2 3. The dates of the letter(s); and
- 3 4. To whom the letter(s) were sent.

4 Please also attach copies of all letters sent to medical professionals and/or “Dear Doctor”
5 and/or “Dear healthcare provider” letters.

6 **Response to Interrogatory No. 45:**

7 NNI incorporates, as if fully set forth herein, the General Objections by reference.
8 NNI objects to this interrogatory as vague and ambiguous as it fails to define certain
9 terms and phrases, including “warning letter” and “medical community.” NNI further
10 objects to this interrogatory to the extent it seeks information unrelated to the alleged
11 risks and injuries at issue in this litigation. NNI further objects to the extent this
12 interrogatory requests information concerning activities outside the United States. NNI
13 further objects to the extent this requests case-specific information, more appropriate for
14 case-specific discovery.

15 Subject to and without waiving or otherwise limiting the foregoing general and
16 specific objections, and pursuant to the parties’ agreement on February 3, 2014, NNI will
17 answer this interrogatory more fully at a later time, as needed, once its discovery and
18 document production are more substantially completed and upon mutual agreement by
19 the parties regarding, among other things, the appropriate scope and context of this
20 request.

21
22 **Reason Why the Answer Should be Provided:**

23 The details behind “Dear Doctor” letters are important because the reasons for
24 their preparation are geared to science issues, and the people responsible for issuing them
25 are potential sources of further discoverable information. Defendant relies on foreign
26 studies and activities (including EMA), and cannot shield itself from foreign discovery.
27 The relevant issues on science and general causation are the same here and abroad.

1 **Basis for Nondisclosure:**

2
3 **INTERROGATORY NO. 46:**

4 Did YOU or anyone on YOUR behalf communicate with any physician concerning
5 VICTOZA and its potential for adverse events, including but not limited to cancers,
6 pancreatitis, other severe personal injuries and/or death? If so, provide:

- 7 a. The date of the communication(s);
8 b. The manner by which the communication(s) took place;
9 c. The substance of the communication(s);
10 d. Why the communication(s) were made; and
11 e. The identity of the person(s) acting on YOUR behalf who made and/or
12 issued the communication(s).

13 Please provide copies of all such communications. If the communications exist in
14 electronic format, produce them in their native electronic format.

15 **Response to Interrogatory No. 46:**

16 NNI incorporates, as if fully set forth herein, the General Objections by reference.
17 NNI objects to this interrogatory as vague and ambiguous. NNI further objects to this
18 interrogatory to the extent it seeks information unrelated to the alleged risks and injuries
19 at issue in this litigation. NNI further objects to the extent this interrogatory requests
20 information concerning activities outside the United States. NNI further objects to the
21 extent this interrogatory requests case-specific information, more appropriate for case-
22 specific discovery.

23 Subject to and without waiving or otherwise limiting the foregoing general and
24 specific objections, and pursuant to the parties' agreement on February 3, 2014, NNI will
25 answer this interrogatory more fully at a later time, as needed, once its discovery and
26 document production are more substantially completed and upon mutual agreement by
27 the parties regarding, among other things, the appropriate scope and context of this
28 request.

1
2
3 **Reason Why the Answer Should be Provided:**

4 Communications with doctors about pancreatitis and pancreatic cancer are very
5 likely to be science-driven, which makes the information requested about those
6 communications discoverable. Defendant relies on foreign studies and activities
7 (including EMA), and cannot shield itself from foreign discovery. The relevant issues on
8 science and general causation are the same here and abroad.
9

10 **Basis for Nondisclosure:**
11
12

13 **INTERROGATORY NO. 47:**

14 Please state whether there have been any changes or discussions of changes to the
15 warnings associated with VICTOZA within the last year. If YOUR answer is in the
16 affirmative, please specify:

- 17 a. The areas in which any changes were implemented;
18 b. The reason behind any changes;
19 c. The dates of any changes;
20 d. The studies, if any, that supported and/or prompted the changes;
21 e. Any and all other information that supported and/or prompted the
22 changes; and
23 f. As to discussions of changes to warnings, describe in detail the nature of
24 the changes considered, and specifically state whether there have been
25 any references to potentially placing a black box warning on VICTOZA.

26 **Response to Interrogatory No. 47:**

27 NNI incorporates, as if fully set forth herein, the General Objections by reference.
28 NNI further objects to this interrogatory to the extent it seeks information unrelated to the

1 alleged risks and injuries at issue in this litigation. NNI further objects to the extent this
2 interrogatory requests information concerning activities outside the United States. NNI
3 further objects to this interrogatory to the extent it requests information outside of the
4 relevant time period.

5 Subject to and without waiving or otherwise limiting the foregoing general
6 and specific objections, NNI directs Plaintiffs to its submissions and communications with
7 the FDA, produced at Bates ranges NNI-IND-61040-00000001 – NNI-IND-61040-
8 00059607 and NNI-NDA-22341-00000001 – NNI-NDA-22341-01380778.

9
10 **Reason Why the Answer Should be Provided:**

11 The controversy over the incretin medications has exploded over the last year. The
12 information requested in this interrogatory regarding potential warnings changes in that
13 time frame (reasons for change, studies relied on, nature of discussions, etc.) is basic
14 information in this case and should have been provided long ago. Instead, defendant
15 provides only a document dump of 59,607 + 1,380,778 pages. Plaintiffs do not believe
16 the “burden of deriving or ascertaining the answer will be substantially the same” for
17 them as for defendant, as required by Rule 33(d), if they have to read every page to get
18 the answers to this question and its subparts.

19 Again, Defendant relies on foreign studies and activities (including EMA), and
20 cannot shield itself from foreign discovery. The relevant issues on science and general
21 causation are the same here and abroad.

22
23 **Basis for Nondisclosure:**

24
25
26 **INTERROGATORY NO. 48:**

1 At any time since VICTOZA became publicly available in the United States, have
2 YOU discussed or considered withdrawing it from the market due to reports of adverse
3 events or for any other reason? If YOUR answer is in the affirmative, please state:

- 4 a. When withdrawal was discussed or considered;
5 b. Who was involved in any discussions regarding withdrawal;
6 c. What prompted any discussions regarding withdrawal;
7 d. Whether any studies were undertaken or reviewed in discussing or
8 considering withdrawal and, if so, identify which ones; and
9 e. Why it was determined not to withdraw VICTOZA from the United
10 States market.

11
12 **Response to Interrogatory No. 48:**

13 NNI incorporates, as if fully set forth herein, the General Objections by reference.
14 NNI objects to the extent this interrogatory requests information concerning activities
15 outside the United States. NNI further objects to this interrogatory to the extent it is
16 unduly burdensome.

17 Subject to and without waiving or otherwise limiting the foregoing general and
18 specific objections, and pursuant to the parties' agreement on February 3, 2014, NNI will
19 answer this interrogatory more fully at a later time, as needed, once its discovery and
20 document production are more substantially completed and upon mutual agreement by
21 the parties regarding, among other things, the appropriate scope and context of this
22 request.

23
24 **Reason Why the Answer Should be Provided:**

25 This is a simple question, and since any discussion of product withdrawal is
26 virtually certain to be science driven, it is clearly relevant. If withdrawal of the
27 medication has been considered, the requested information should be provided. If
28 withdrawal has not been considered, it is easy to state as much. Again, Defendant relies

1 on foreign studies and activities (including EMA), and cannot shield itself from foreign
2 discovery. The relevant issues on science and general causation are the same here and
3 abroad.

4
5 **Basis for Nondisclosure:**

6
7
8 **INTERROGATORY NO. 49:**

9 Has there ever been a discontinuance, either temporary or otherwise, of any
10 exenatide, sitagliptin, liraglutide and/or any other GLP-1 agonist or DPP-4 inhibitor-
11 containing medication in the United States or any other country? If YOUR answer is in
12 the affirmative, indicate the following:

- 13 a. Which drug(s) were removed from the market;
14 b. When the removal(s) occurred;
15 c. Whether the discontinuance(s) were permanent or temporary;
16 d. The primary motivations behind the discontinuance(s); and,
17 e. The rate of discontinuance in comparison to the overall prevalence of the
18 drug(s) on the market.

19
20 **Response to Interrogatory No. 49:**

21 NNI incorporates, as if fully set forth herein, the General Objections by reference.
22 NNI objects to this interrogatory as vague and ambiguous. NNI further objects to this
23 interrogatory to the extent it seeks information unrelated to the alleged risks and injuries
24 at issue in this litigation. NNI further objects to this interrogatory to the extent it seeks
25 information concerning products other than Victoza®. NNI further objects to the extent
26 this interrogatory requests information regarding foreign regulatory activities.

27 Subject to and without waiving or otherwise limiting the foregoing general and
28 specific objections, and pursuant to the parties' agreement on February 3, 2014, NNI will

1 answer this interrogatory more fully at a later time, as needed, once its discovery and
2 document production are more substantially completed and upon mutual agreement by
3 the parties regarding, among other things, the appropriate scope and context of this
4 request.

5
6 **Reason Why the Answer Should be Provided:**

7 This is again a simple question, and since any product discontinuance is virtually
8 certain to be science driven, it is clearly relevant. If defendant's product has been
9 discontinued in any market, the requested information should be provided. The same
10 issues apply across all of the incretin medications, so if defendant has information about
11 the discontinuance of another company's incretin drugs, that information is also relevant
12 and should be provided. If defendant does not have such information for other
13 medications, it can easily state as much.

14 Defendant relies on foreign studies and activities (including EMA), and cannot
15 shield itself from foreign discovery. The relevant issues on science and general causation
16 are the same here and abroad.

17
18 **Basis for Nondisclosure:**

19
20
21 DATED: March 7, 2014.

PLAINTIFFS' COUNSEL

22
23 /s/ Michael K. Johnson

24 Michael K. Johnson

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