

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN N-
NITROSODIMETHYLAMINE (NDMA),
LOSARTAN, and IRBESARTAN PRODUCTS
LIABILITY LITIGATION

Civil No. 19-2875 (RBK/JS)

ORDER

The Court having held numerous conferences with the parties to finalize the remaining Fact Sheets to be served and answered; and this Order intending to approve these Fact Sheets; and the Court noting that objections to the Fact Sheets are barred; and accordingly,

IT IS HEREBY ORDERED this 6th day of August, 2020 as follows:

1. Attached as Exhibit A is the Court approved "Finished Dose Manufacturer Defendants' Fact Sheet";
2. Attached as Exhibit B is the Court approved "API Manufacturer Defendants' Fact Sheet";
3. Attached as Exhibit C is the Court approved "Wholesaler, Repackager, and Relabeler Defendants' Fact Sheet";
4. Attached as Exhibit D is the Court approved "Pharmacy Defendants' Exemplar Fact Sheet"; and it is further

ORDERED the foregoing fact sheets shall be answered by the

deadlines in the Orders entered on May 29, 2020 [Doc. No. 452] and July 29, 2020 [Doc. No. 532].

s/Joel Schneider
JOEL SCHNEIDER
United States Magistrate Judge

Exhibit A

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

IN RE: VALSARTAN, LOSARTAN,
AND IRBESARTAN PRODUCTS
LIABILITY LITIGATION

No. 1:19-md-2875-RBK
Hon. Robert Kugler
Hon. Joel Schneider

**FINISHED DOSE
MANUFACTURER
DEFENDANTS' FACT SHEET**

In accordance with the Court's January 30, 2020 Order (Dkt. 360) and May 29, 2020 Order (Dkt. 452), within 60 days of completion of a Defendants' Fact Sheet by all Distributor, Repackager, Relabeler, and Wholesaler Defendants, each finished dose manufacturer Defendant ("Finished Dose Manufacturer Defendant") identified in the applicable Plaintiff Fact Sheet ("PFS") must complete and serve this Defendant Fact Sheet ("DFS") on each Plaintiff's counsel identified in the PFS and on the Plaintiffs' Executive Committee through MDL Centrality. Further, no Defendant will be required to serve a DFS until Plaintiff supplies a substantially completed and verified PFS. The determination whether a PFS is "substantially complete" shall be made in accordance with the process set forth in the Court-approved PFS (CMO 16).

Each response must provide the substantive information requested to the extent the information is reasonably accessible to the responding Defendant as maintained in the ordinary course of business, or, if applicable, the responding Defendant may produce or cite to produced documents or business records by Bates number in accordance with Federal Rule of Civil Procedure 33(d).

In filling out this form, Defendants must respond on the basis of information and/or documents that are reasonably available to the Defendant and use the following definitions:

"AFFECTED DRUGS": The Valsartan-containing drugs identified in the PFS and confirmed by attached pharmacy records, to the extent lot, batch, NDC codes or other identifiers allow confirmation of drug source. If a Finished Dose Manufacturer Defendant cannot conclude that they manufactured the Valsartan-containing drug, they shall so state herein.

"AFFECTED API": The Valsartan API for any Affected Drug(s).

"DOCUMENTS": "Documents" as used in this request is coextensive with the meaning of the terms "documents," "electronically stored information" and "tangible things" as used in the Federal Rules of Civil Procedure, and shall have the broadest possible meaning and interpretation ascribed to those terms. To the extent "Documents" refers to electronically stored information, the scope shall be interpreted as consistent with the scope of communications contemplated by the Electronic Discovery Protocol (Dkt. 127) agreed to by the parties.

“PLAINTIFF”: Means the Plaintiff who took valsartan-containing drugs in the individual action to which this DFS relates.

“YOU,” “YOUR,” or “YOURS”: Means the responding Defendant.

I. CASE INFORMATION

This DFS pertains to the following case: _____
Case Name and Docket Number

Date that this DFS was completed: _____

Defendant completing this DFS: _____

II. FINISHED DOSE MANUFACTURERS

A. Based on the information provided by Plaintiff through the PFS and by other Defendants through their responses to the DFS, can you determine that you manufactured any Affected Drug(s)?

Yes ____ No ____

If yes, identify the Affected Drug(s) you have determined that you manufactured by NDC Code:

B. If you answered yes to II.A, with the information provided by Plaintiff through the PFS and by other Defendants through their responses to the DFS, can you identify the batch or lot number for any Affected Drug(s) that you manufactured?

Yes ____ No ____

If yes, provide (i) the batch or lot number for the Affected Drug(s) that you manufactured, (ii) identify and provide the results of all nitrosamine testing you performed on the Affected API and/or Affected Drugs, and (iii) state whether or not the Affected API and/or Affected Drugs were recalled and the date of the recall.

C. For each Affected Drug identified in response to Question II.A or II.B, identify the manufacturer of the Affected API.

D. For each Affected Drug listed in response to Question II.B, provide the date the finished dose drug was manufactured, the place of manufacture (by facility, city, state/province, and country), and the date of expiry or retest period for the Affected Drug(s).

E. Identify the entity or entities from which you purchased the Affected API used in the Affected Drug(s) listed in response to Question II.A and II.B and the date on which each purchase occurred.

- F. Identify the entity or entities to which you sold or distributed each Affected Drug listed in response to Question II.B and the date on which each sale or distribution occurred.
- G. State whether you supplied each test result identified in response to Question II.B to the FDA, your actual customers, or other Defendants, and, if so, identify the test result, and provide the recipient of the test result, date of communication and content of the communication.
- H. Provide the date(s) on which you sent any recall notice to any Defendants or pharmacies identified in the PFS, or any of your actual or prospective customers of the Affected Drugs listed in response to Question II.A, including, but not limited to, pharmacy benefits managers, and attach the recall notice(s).
- I. Were any Affected Drugs listed in response to Question II.A or II.B returned to you or retained by you for any reason, and do any Affected Drugs listed in response to Question II. A or II.B still exist?

Yes _____ No _____

If yes, please identify and produce:

- a. The date you regained possession or control of the drugs, if returned to you;
 - b. The current location of the drugs;
 - c. If any, the date and result of any nitrosamine-related testing done on the returned or retained drugs, as by the Court’s Order on macro discovery (Dkt. 303, ¶ 8). and
 - d. If not returned to you, but you have knowledge of the location of the drugs, provide the location:
- J. *Answer only if Plaintiffs answered “yes” to question III.B.7 in the PFS:* Have you ever been contacted through the customer call or contact centers by Plaintiff or by anyone acting on behalf of Plaintiff (other than Plaintiff’s counsel) at any time from the date Plaintiff began taking valsartan-containing drugs through the present?

Yes _____ No _____ Don’t know _____

If yes, produce all Documents evidencing that contact including video or audio recording of such contacts.

VERIFICATION

I am Legal Counsel for _____, a Defendant named in this litigation. I am authorized by this Defendant to execute this certification on each corporation's behalf. I hereby certify that the information provided in the accompanying Response to Defendants' Fact Sheet is not within my personal knowledge, but the facts state therein have been assembled by authorized employees and counsel, upon which I relied. I hereby certify, in my authorized capacity, that the responses to the aforementioned Defendants' Fact Sheet are true and complete to the best of my knowledge on information and belief.

Date: _____

Signature

Name: _____

Employer: _____

Title: _____

Exhibit B

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

IN RE: VALSARTAN, LOSARTAN,
AND IRBESARTAN PRODUCTS
LIABILITY LITIGATION

No. 1:19-md-2875-RBK
Hon. Robert Kugler
Hon. Joel Schneider

**API MANUFACTURER
DEFENDANTS' FACT SHEET**

In accordance with the Court's January 30, 2020 Order (Dkt. 360) and May 29, 2020 Order (Dkt. 452), within 60 days of completion of a Defendants' Fact Sheet by the Finished Dose Manufacturer Defendants, the API manufacturer Defendants ("API Manufacturer Defendants") identified in the applicable Plaintiff Fact Sheet ("PFS") must complete and serve this Defendant Fact Sheet ("DFS") on each Plaintiff's counsel identified in the PFS and on the Plaintiffs' Executive Committee through MDL Centrality. Further, no Defendant will be required to serve a DFS until Plaintiff supplies a substantially completed and verified PFS. The determination whether a PFS is "substantially complete" shall be made in accordance with the process set forth in the Court-approved PFS (CMO 16).

Each response in this DFS must provide the substantive information requested to the extent the information is reasonably accessible to the responding Defendant as maintained in the ordinary course of business, or, if applicable, the responding Defendant may produce or cite to produced documents or business records by Bates number in accordance with Federal Rule of Civil Procedure 33(d).

In filling out this form, Defendants must respond on the basis of information and/or documents that are reasonably available to the Defendant and use the following definitions:

"AFFECTED DRUGS": The Valsartan-containing drugs identified in the PFS and confirmed by attached pharmacy records, to the extent lot, batch or other identifiers allow confirmation of drug source. If an API Manufacturer Defendant cannot conclude that they provided the API for an Affected Drug, they shall so state herein.

"AFFECTED API": The Valsartan API for any Affected Drug(s).

"DOCUMENTS": "Documents" as used in this request is coextensive with the meaning of the terms "documents," "electronically stored information" and "tangible things" as used in the Federal Rules of Civil Procedure, and shall have the broadest possible meaning and interpretation ascribed to those terms. To the extent "Documents" refers to electronically stored information, the scope shall be interpreted as consistent with the scope of communications contemplated by the Electronic Discovery Protocol (Dkt. 127) agreed to by the parties.

“PLAINTIFF”: Means the Plaintiff who took valsartan-containing drugs in the individual action to which this DFS relates.

“YOU,” “YOUR,” or “YOURS”: Means the responding Defendant.

I. CASE INFORMATION

This DFS pertains to the following case: _____
Case Name and Docket Number

Date that this DFS was completed: _____

Defendant completing this DFS: _____

II. API MANUFACTURERS

A. Based on the information provided by Plaintiff through the PFS and by other Defendants through their responses to the DFS, can you determine that you manufactured Affected API used in any Affected Drug(s)?

Yes ____ No ____

If yes, identify the Affected Drugs you have determined contain Affected API that you manufactured by NDC Code:

B. If yes, with the information provided by Plaintiff through the PFS and by other Defendants through their responses to the DFS, can you identify the batch or lot number for any Affected API that you manufactured?

Yes ____ No ____

If yes, provide (i) the batch or lot number for the Affected API that you manufactured and identify the corresponding Affected Drug(s); (ii) identify and provide the results of all nitrosamine testing you performed on the Affected API, and (iii) state whether or not the Affected API was recalled and the date of the recall.

C. For each Affected API listed in response to Question II.A and B, identify whether any dimethylformamide, o xylene, or toluene used in the manufacture of these APIs was recycled or recovered, if so, identify the recycled solvent, the entity(ies) that supplied the solvent, and on which date those solvents were used to manufacture the Affected API.

D. For each Affected API listed in response to Question II.A and B, provide the date the API was manufactured, the place of manufacture (by facility, city,

state/province, and country), and the date of expiry or retest period for the Affected API.

- E. Identify the entity or entities to which you sold or distributed each Affected API listed in response to Question II.A and the date on which each sale or distribution occurred.
- F. State whether you supplied each test result identified in response to Question II.A or B to the FDA, your actual customers, or other Defendants, and, if so, identify the test result and provide the recipient of the test result, date of communication, and content of the communication.
- G. Provide the date(s) on which you sent any recall notice that applied to any Affected API to any Defendants or pharmacies identified in the PFS, or any of your actual or prospective customers of the Affected API listed in response to Question II.A or B, and attach the recall notice(s).
- H. Were any Affected Drugs listed in response to Question II.A or II.B returned to you or retained by you, and does any Affected API listed in response to Question II.B still exist?

Yes _____ No _____

If yes, please identify and produce:

The date you regained possession or control of the Affected API, if returned to you;

If any, the date and result of any nitrosamine-related testing done on the returned or retained drugs, as by the Court's Order on macro discovery issues (Dkt. 303, ¶ 8); and

The current location of the Affected API.

If not returned to you, but you have knowledge of the location of the drugs, provide the location:

- I. *Answer only if Plaintiffs answered "yes" to question III.B.7 in the PFS:* Have you been contacted through customer call or contact centers by Plaintiff or by anyone acting on behalf of Plaintiff (other than Plaintiff's counsel) at any time from the date Plaintiff began taking valsartan-containing drugs through the present?

Yes _____ No _____ Don't Know _____

If yes, produce all Documents evidencing that contact including video or audio recording of such contacts.

VERIFICATION

I am Legal Counsel for _____, a Defendant named in this litigation. I am authorized by this Defendant to execute this certification on each corporation's behalf. I hereby certify that the information provided in the accompanying Response to Defendants' Fact Sheet is not within my personal knowledge, but the facts state therein have been assembled by authorized employees and counsel, upon which I relied. I hereby certify, in my authorized capacity, that the responses to the aforementioned Defendants' Fact Sheet are true and complete to the best of my knowledge on information and belief.

Date: _____

Signature

Name: _____

Employer: _____

Title: _____

Exhibit C

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

IN RE: VALSARTAN, LOSARTAN,
AND IRBESARTAN PRODUCTS
LIABILITY LITIGATION

No. 1:19-md-2875-RBK
Hon. Robert Kugler
Hon. Joel Schneider

**WHOLESALE,
REPACKAGER, AND
RELABELER DEFENDANTS'
FACT SHEET**

In accordance with Case Management Order No. ___, within 60 days of completion of a Defendants' Fact Sheet by all Pharmacy or Retailer Defendants, each Wholesaler, Repackager, and Relabeler Defendant ("Wholesaler/Repackager/Relabeler Defendants" or "These Defendants") identified in a Defendant Fact Sheet by any Retailer or Pharmacy as an entity in the chain of distribution for drugs purchased and/or consumed by a particular Plaintiff must complete and serve this Defendant Fact Sheet ("DFS") on each Plaintiff's counsel identified in the PFS and on the Plaintiffs' Executive Committee through MDL Centrality. Further, no Defendant will be required to serve a DFS until Plaintiff supplies a substantially completed and verified PFS. The determination whether a PFS is "substantially complete" shall be made in accordance with the process set forth in the Court-approved PFS (CMO 16).

Each response must provide the substantive information requested to the extent the information is reasonably accessible to the responding Defendant as maintained in the ordinary course of business, or, if applicable, the responding Defendant may produce or cite to produced documents or business records by Bates number in accordance with Federal Rule of Civil Procedure 33(d).

In filling out this DFS, each of These Defendants must respond on the basis of information and/or documents that are reasonably available to each of These Defendants and use the following definitions:

"AFFECTED DRUGS": The Defendant-manufactured Valsartan-containing drugs identified in the PFS and confirmed by attached pharmacy records, by NDC code, and to the extent available, lot, batch, and/or other identifiers that allow confirmation of drug source.

"SUBJECT TIME PERIOD(S):" With regard to purchases of the Affected Drug or sales of the Affected Drugs to a particular Relevant Pharmacy Defendant, the six months before the plaintiff first purchased the Affected Drug from that Relevant Pharmacy Defendant until thirty days after the plaintiff purchased the last Affected Drug from that Relevant Pharmacy Defendant, as listed in

the plaintiff's PFS or attached pharmacy records. For clarity, there may be multiple Subject Time Periods for a single PFS.

“DOCUMENTS”: “Documents” as used in this request is coextensive with the meaning of the terms “documents,” “electronically stored information” and “tangible things” as used in the Federal Rules of Civil Procedure, and shall have the broadest possible meaning and interpretation ascribed to those terms. To the extent “Documents” refers to electronically stored information, the scope shall be interpreted as consistent with the scope of communications contemplated by the Electronic Discovery Protocol (Dkt. 127) agreed to by the parties.

“PLAINTIFF”: Means the plaintiff who took valsartan-containing drugs in the individual action and completed the PFS to which this DFS relates.

“RELEVANT PHARMACY DEFENDANTS” means the pharmacies from which the plaintiff purchased Affected Drug(s) and which are identified in the PFS and/or through attached Pharmacy Records

“YOU,” “YOUR,” or “YOURS”: Means the responding Defendant.

CASE INFORMATION

This DFS pertains to the following case: _____

Case Name and Docket Number

Date that this DFS was completed: _____

Defendant completing this DFS: _____

A. Based on the information provided by Plaintiff through the PFS and by the Retail Pharmacy Defendants identified therein, through their related DFS responses and through Your information, did you sell and/or distribute any of the Affected Drug(s) that were provided to the subject Plaintiff?

Yes ___ No ___ Cannot Determine ___

If your answer is Cannot Determine, please explain why:

1. Based on that same information, did you sell and/or distribute any of the Affected Drug(s) that were provided to the pharmacies identified in the PFS and attached pharmacy records provided by the subject Plaintiff?

Yes ___ No ___ Cannot Determine ___

If your answer is Cannot Determine, please explain why: _____

- B. If your answer to Question A(1)) was “yes:”
1. Identify by NDC code, lot, batch, date of sale, quantity, expiry date, purchaser, and location shipped each sale of an Affected Drug by You to the Relevant Pharmacy Defendant(s) during the Subject Time Period(s).
 2. Identify by NDC code, lot, batch, seller, date of purchase, and quantity, each purchase of an Affected Drug by You during the Subject Time Period(s).
 3. Identify any testing, including the full results, done on that batch or lot of Affected Drug(s) listed in response to Question B.1 and B.2 that You were provided or conducted:
 - a. to identify impurities; or
 - b. to identify nitrosamines, and/or that identified any impurity or artifact, including but not limited to a nitrosamine.
 4. State whether You supplied each test result identified in response to Question B.3 to the FDA or to any other entity or person (e.g., your actual or prospective customers), and, if so, identify the test result, and provide the recipient of the test result, date of communication and content of the communication.
 5. Provide the date(s) on which You sent any recall notice to any Plaintiff, Plaintiff’s Prescribing Physician/Clinic or Relevant Pharmacy Defendants identified in the PFS.

C. Were any Affected Drugs returned to You by Plaintiff or a Relevant Pharmacy Defendant at any time during the Subject Time Period(s)?

Yes _____ No _____

1. If returned to You, provide the date of such return and by whom the Affected Drugs were returned;
2. If returned to You, provide the current location of the returned Affected Drugs;
3. If returned to You, provide the date and result of any nitrosamine-related testing done by You on any returned Affected Drugs, if any.
4. To the extent You performed testing on the returned Affected Drug, state whether You supplied each test result identified in response to Question C.3 to the FDA or to any other entity or person (e.g., your actual or prospective customers), and, if so, identify the test result, and provide the

recipient of the test result, date of communication and content of the communication.

- D. *Answer only if Plaintiffs answered “yes” to question III.B.7 in the PFS:* Have You ever been contacted through the customer call or contact centers by Plaintiff or by anyone acting on behalf of Plaintiff (other than Plaintiff’s counsel) at any time from the date Plaintiff began taking the Affected Drugs through the present?

Yes ____ No ____ Cannot Determine ____

If yes, produce all non-privileged Documents evidencing that contact including video or audio recording of such contacts.

- E. Produce any non-privileged document You created before the filing of this lawsuit which relates to or refers to the specific Plaintiff identified in the PFS.
- F. Subject to limitations set forth in this Fact Sheet concerning timeframes and categories of relevant information, please produce any recall advisory communication You sent to or received from any of Plaintiff’s Prescribing Health Care Providers identified in the PFS and/or Primary Treating Physicians identified in the PFS. To the extent the exact copy of any such communication is not reasonably available, please produce the template of any such letter.

VERIFICATION

I am a duly authorized representative of _____, a Defendant named in this litigation. I am authorized by this Defendant to execute this certification on the corporation's behalf. I hereby certify that, while the information provided in the accompanying Response to Defendant's Fact Sheet is not within my personal knowledge, the facts stated therein have been assembled by authorized employees and counsel, upon which I relied. I hereby certify, in my authorized capacity, that the responses to the aforementioned Defendants Fact Sheet are true and complete to the best of my knowledge on information and belief.

Date: _____

Signature

Name: _____

Employer: _____

Title: _____

Exhibit D

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

IN RE: VALSARTAN, LOSARTAN,
AND IRBESARTAN PRODUCTS
LIABILITY LITIGATION

No. 1:19-md-2875-RBK
Hon. Robert Kugler
Hon. Joel Schneider

**PHARMACY DEFENDANTS'
EXEMPLAR DEFENDANT
FACT SHEET**

In accordance with Case Management Order No. __, within 60 days of completion of a Plaintiff's Fact Sheet, each Pharmacy or Retailer Defendant ("Pharmacy Defendant") identified in the applicable Plaintiff Fact Sheet ("PFS") must complete and serve this Exemplar Defendant Fact Sheet ("EDFS") on each Plaintiff's counsel identified in the PFS and on the Plaintiffs' Executive Committee through MDL Centrality. This EDFs applies only to those cases specifically referenced in the Court's January 30, 2020 Order (Dkt. 360), which limited the Pharmacy Defendants' Fact Sheet obligations to: (1) Defendant Fact Sheets produced in response to Plaintiff Fact Sheets submitted by putative class representatives; and (2) to a representative group of 20 personal injury plaintiffs, to be identified by the Plaintiffs' Executive Committee.¹

The 60-day time period for each Pharmacy Defendant to prepare and produce an EDFs shall begin no earlier than (1) August 15 for the putative class representative plaintiffs; and (2) August 31 for the personal injury plaintiffs, provided Plaintiffs' Executive Committee has identified those plaintiffs to counsel for the Pharmacy Defendants by that date. Further, and consistent with the terms of the Court-approved PFS, entered October 28, 2019 (Dkt. 283), no Defendant will be required to serve an EDFs until Plaintiff supplies a substantially completed and verified PFS. The determination whether a PFS is "substantially complete" shall be made in accordance with the process set forth in the Court-approved PFS (CMO 16). Plaintiffs understand that the Pharmacy Defendants have coordinated with all Wholesaler and Manufacturer Defendants in any cases in which they are named to review Plaintiff Fact Sheets and identify any deficiencies, and that the Defendants have and will continue to serve joint deficiency notices as to each PFS served. Defendants will continue to use this coordinated process for identifying PFS deficiencies, and nothing shall prohibit the Pharmacy Defendants from continuing to rely on a coordinated deficiency notice for purposes of arguing that a PFS is not substantially complete.

¹ The Pharmacy Defendants' position is that the questions set forth herein may be unduly burdensome if the Pharmacy Defendants are required to answer these same questions for all Plaintiffs in this litigation, rather than the initial small subset contemplated by the Court's January 30 Order. The Parties agree to meet and confer on the scope and/or deadlines associated with this DFS if the Court orders Defendants to respond to all Plaintiffs' PFS.

Each response must provide the substantive information requested to the extent the information is reasonably accessible to the responding Defendant as maintained in the responding Defendant's central, non-custodial files, and as maintained in the ordinary course of business. The responding Defendant need not search store-level or custodial data for purposes or responding to this DFS. Defendants represent that the information sought herein ordinarily is kept in non-custodial, centrally stored databases, to the extent the information is maintained at all. If applicable, and in lieu of answering the questions set forth below, the responding Defendant may produce and cite to produced documents or business records by Bates number in accordance with Federal Rule of Civil Procedure 33(d).

In filling out this form, Defendants must respond on the basis of information and/or documents that are reasonably available to the Defendant and use the following definitions:

“AFFECTED DRUGS”: The Valsartan-containing drugs identified in the PFS and confirmed by attached pharmacy records, to the extent National Drug Code(s) (NDC) or other identifiers allow confirmation of drug source. For purposes of the EDFs, “Affected Drugs” is limited to only those drugs with a NDC associated with any of the Manufacturer Defendants identified in Plaintiffs’ Master Complaints. If a Pharmacy Defendant cannot conclude that it sold the Valsartan-containing drug identified in a Plaintiff’s PFS, it shall so state herein.

“AFFECTED API”: The Valsartan API for any Affected Drug(s).

“DOCUMENTS”: “Documents” as used in this request is coextensive with the meaning of the terms “documents,” “electronically stored information” and “tangible things” as used in the Federal Rules of Civil Procedure, and shall have the broadest possible meaning and interpretation ascribed to those terms. To the extent “Documents” refers to electronically stored information, the scope shall be interpreted as consistent with the scope of communications contemplated by the Electronic Discovery Protocol (Dkt. 127) agreed to by the parties.

“PLAINTIFF”: Means the Plaintiff who took the Affected Drug in the individual action to which this DFS relates. Plaintiff does not include any estate representative, spouse or other individual asserting derivative or representative claims on behalf of the individual who took the Affected Drugs identified in the PFS.

“YOU,” “YOUR,” or “YOURS”: Means the responding Defendant.

I. CASE INFORMATION

This DFS pertains to the following case: _____
Case Name and Docket Number

Date that this DFS was completed: _____

Defendant completing this DFS: _____

II. PHARMACY DEFENDANTS

A. Based on the information provided by Plaintiff through the PFS, can you determine that you sold and/or dispensed any Affected Drug(s)?

Yes ____ No ____

B. If your answer to Question II(A) was “yes,” please produce dispensing records and/or provide information from your centrally stored records sufficient to identify the following information. To the extent the dispensing records in your possession responsive to this question are identical to those already produced by the Plaintiff with his/her PFS and contain the information set forth below, you may state as much below.²

1. The NDC of the Affected Drug(s) you determined that you sold and/or dispensed to Plaintiff, and the entity to whom the NDC is registered;
2. Identify the manufacturer of the Affected API.
3. The name and address of the stores (or remote order fulfilment location) that dispensed the Affected Drug(s), including any store identifiers (e.g., Pharmacy No. 123);
4. The date(s) on which the Affected Drug(s) were dispensed.
5. The batch number, lot number, and expiry date for Affected Drugs dispensed on each dispensation date;
6. The quantity of Affected Drug(s) dispensed on each dispensation date.
7. The amounts paid by Plaintiff for the Affected Drug(s) on each dispensation date; and
8. Which of the Affected Drug(s) were recalled by you, if any, and the date(s) of recall.

² To the extent you rely on this provision in lieu of producing dispensing records, you must agree to stipulate to the authenticity of the dispensing records.

- C. Identify the entity or entities from which you purchased each Affected Drug(s) listed in response to Question II(A) and (B), the full chain of distribution as high in the distribution chain as your records or other information available to you demonstrate for each Affected Drug. In responding to this question, you may refer to any purchase records produced by you in response to Request for Production No. 1 of Plaintiffs' Second Amended Set of Requests for Production of Documents to the Retail Pharmacy Defendants (Dkt. 508-1). To the extent you refer to any such production, your response should contain sufficient information to permit the reviewing party to locate the data contained in any document referred to in your response.
- D. Did you send any recall communication to the Plaintiff regarding any recall of Valsartan and/or any potential Valsartan impurities? If yes, provide the date(s) on which you sent such communication to the Plaintiff. If available, provide a copy of the communication(s), letter(s), or template letter(s) sent to the Plaintiff relating to any recall of Valsartan and/or any potential Valsartan impurities. If no such copy of the communication(s) or letter(s) sent to the Plaintiff is available, state as much in your response to this question.
- E. Did Plaintiff return any Affected Drugs listed in response to Question II.A or II.B to you due to any product recall?

Yes ___ No ___ Don't know ___

If yes, please identify and produce:

- a. The date you regained possession or control of the drugs, if returned to you;
 - b. The current location of the drugs; and
 - c. The date and result of any nitrosamine-related testing, if any, done by you on the returned or retained drugs, as by the Court's Order on macro discovery (Dkt. 303, ¶ 8).
- F. To the extent you performed testing on the returned Affected Drug, as referenced in Question II.E.c, state whether you supplied each test result identified in response to Question II.E.c to the FDA or to any other entity or person (e.g., your actual or prospective customers), and, if so, identify the test result, and provide the recipient of the test result, date of communication and content of the communication.
- G. *Answer only if Plaintiffs answered "yes" and provided sufficient information in response to question III.B.7 and its subparts in the PFS:* Have you ever been contacted through the customer call or contact centers by Plaintiff or by anyone acting on behalf of Plaintiff (other than Plaintiff's counsel) regarding the Affected Drugs at any time from the date Plaintiff began taking valsartan-containing drugs through the present?

Yes ____ No ____ Don't know ____

If yes, produce all Documents evidencing that contact, including video or audio recording of such contacts.

- H. Produce any document created before the filing of this lawsuit that refers to Plaintiff and the contamination or recall of Valsartan, other than documents received or produced in discovery in this matter. You need not search for or produce record authorization requests in responding to this question. In responding to this request, Defendants will search and produce responsive documents from their customer call center records, customer contact center records, and central complaint files.
- I. Subject to limitations set forth in this fact sheet concerning timeframes and categories of relevant information, please produce any recall advisory communication regarding the Affected Drug sent to or received from any of Plaintiff's Prescribing Health Care Providers identified in the PFS and/or Primary Treating Physician identified in the PFS. To the extent the exact copy of any such communication is not reasonably available, please produce the template of any such letter.

VERIFICATION

I am Legal Counsel for _____, a Defendant named in this litigation. I am authorized by this Defendant to execute this certification on each corporation's behalf. I hereby certify that the information provided in the accompanying Response to Defendants' Fact Sheet is not within my personal knowledge, but the facts state therein have been assembled by authorized employees and counsel, upon which I relied. I hereby certify, in my authorized capacity, that the responses to the aforementioned Defendants' Fact Sheet are true and complete to the best of my knowledge on information and belief.

Date: _____

Signature

Name: _____

Employer: _____

Title: _____