

**UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION**

IN RE: TASIGNA (NILETINIB)
PRODUCTS LIABILITY LITIGATION

Case No. 6:21-md-3006-RBD-DAB
(MDL No. 3006)

This document relates to all actions.

ORDER IMPLEMENTING DEFENDANT FACT SHEET

Before the Court are the parties' joint proposed Defendant Fact Sheet (Doc. 28-1), Plaintiffs' proposed order implementing the Defendant Fact Sheet (Doc. 28-2), and Defendant's proposed order implementing the Defendant Fact Sheet (Doc. 28-3). The final Defendant Fact Sheet ("DFS") is attached hereto as Exhibit 1. As the Court advised at the hearing (Doc. 46) and in Pretrial Order No. 3 (Doc. 47, pp. 1-2), the Court rejects Defendant's proposed order implementing the DFS and largely adopts the Plaintiffs' proposed order, with some changes made by the Court.

As such, it is **ORDERED AND ADJUDGED:**

A. Scope of Order

This Order is binding on all parties and their counsel in all cases currently pending or subsequently made part of this MDL and shall govern each case therein.

The obligation to comply with this Order and to provide a DFS, or to take

any action authorized in this Order related to deficiencies in a DFS, shall be the sole obligation of the individual attorney hired by the individual Plaintiff. As with all case-specific discovery, the members of the Plaintiffs' MDL leadership are not obligated to conduct case-specific discovery for Plaintiffs by whom they have not been individually retained in any manner.

B. Defendant Fact Sheet and Responsive Documents

The parties have agreed upon a DFS that includes document requests. *See* Exhibit 1. In accordance with the schedule set forth below, Defendant shall complete and execute a DFS for use in all proceedings and produce to Plaintiffs all records required under the DFS.

Defendant's responses to the DFS shall be treated as answers to interrogatories under Fed R. Civ. P. 33 and shall be signed by a representative of Defendant. The responses to requests for production of documents included in the DFS are made under Fed. R. Civ. P. 34 and need only be signed by counsel.

All objections to the admissibility of information contained in the DFS are reserved and therefore no objections shall be lodged in the response to the questions and document requests contained in the DFS.

C. Production from Sales Force Custodial Files

The parties have agreed that in responding to the document demands in the DFS, Defendant will not search or produce documents from any sales force

custodial files. Any such production from sales force custodial files will be deferred until the identification of a discovery pool, or the commencement of case-specific discovery in a particular case, at which time the parties will meet and confer regarding the scope and timing of the production. Further, the parties have agreed that if information responsive to the DFS cannot be obtained from non-custodial sources, the parties will meet and confer in good faith to resolve the issue.

D. Schedule of Production of DFS

Defendant shall complete and serve a DFS within thirty (30) days of receipt of a Plaintiff Fact Sheet (“PFS”).

The Court reminds Defendant, as it did at the hearing (*see* Doc. 46), that any perceived deficiency in the PFS is not sufficient reason to withhold production of the Defendant Fact Sheet (“DFS”). The Court reminds Plaintiffs, as it did at the hearing, that it expects each PFS to be substantially complete. Any perceived deficiencies should be brought to the Court’s attention immediately via a joint submission.

E. Service

Defendant shall complete and serve its DFS and responsive documents by emailing them to counsel of record.

F. Non-Compliance with DFS Requirements

Defendant shall make a good faith effort to respond to the DFS and provide documents in their possession, custody, or control as required by the DFS, by the applicable deadlines set forth in this Order. The Parties recognize that, despite good faith efforts, certain alleged discovery deficiencies in the DFS responses, including timeliness, may require Court intervention. However, before any such alleged discovery deficiencies are raised with the Court, Plaintiff shall notify Defendant in writing (“Deficiency Letter”) of the alleged deficiency. Defendant shall respond to the alleged deficiency within fourteen (14) days of the date of service of the Deficiency Letter. If Defendant has not provided a completed DFS and/or cured the deficiency within fourteen (14) days after receiving the Deficiency Letter, Plaintiff may seek relief from the Court.

G. Obligations of DFS

Nothing herein shall preclude the parties from serving reasonable case-specific discovery requests in connection with individual cases that have been identified for trial work-up/bellwether process by the Court, and the parties will meet and confer to discuss the scope of such discovery and raise any areas of dispute with the Court.

IT IS SO ORDERED.

DONE AND ORDERED in Chambers in Orlando, Florida, on November 2,
2021.





ROY B. DALTON JR.
United States District Judge

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

IN RE: TASIGNA (NILETINIB)
PRODUCTS LIABILITY LITIGATION

Case No. 6:21-md-3006-RBD-DAB
(MDL No. 3006)

This document relates to all actions.

DEFENDANT FACT SHEET

INSTRUCTIONS

In completing this Defendant Fact Sheet (“DFS”), You are providing this information under oath and must provide information that is true and correct to the best of Your knowledge, recollection, information, and belief. Please answer every question. Do not leave any blanks. You are obligated to amend and/or supplement Your responses in a timely manner if You learn that Your responses are incomplete, incorrect, and/or learn of information or documentation which is responsive, but was not previously included. The DFS shall be completed in accordance with the requirements and guidelines set forth in the applicable Order Implementing DFS.

In addition, the term “produce” shall include, at Defendant’s option, the physical production of documents to Plaintiff’s counsel or the identification of how documents can be located in Defendant’s document production.

DEFINITIONS

Plaintiff: The person who was treated with Tasigna and allegedly sustained an injury caused by Tasigna.

Novartis, You, Your, Yours, Defendant or Defendants: Novartis Pharmaceuticals Corporation (“NPC”).

Tasigna: shall refer, without the need for further reference and without limitation, to the product marketed as Tasigna including all other names it has been known as (*e.g.*, AMN107, nilotinib).

Prescribing Health Care Provider: health care providers identified by Plaintiff in

their Plaintiff Fact Sheet (“PFS”) or Interrogatory Responses who prescribed or dispensed Tassigna.

Marketing Information: as used herein, the term “Marketing Information” includes documentation, including electronically stored information, designating particular campaigns, Promotional Material and/or other promotional efforts directed towards particular types or specialties of healthcare providers (e.g. oncologists) and/or specifically identified healthcare providers. In responding to the document demands in this DFS, NPC will not search or produce documents from any sales force custodial files. Any such production from sales force custodial files will be deferred until the identification of a discovery pool, or the commencement of case-specific discovery in a particular case, at which time the parties will meet and confer regarding the scope and timing of any production.

Prescribing Data: any prescriber-level data available to You that details or summarizes the Tassigna prescribing habits and/or history of the Plaintiff’s Prescribing Health Care Provider(s).

Sales Representative: any person presently or formerly engaged or employed by You whose job duties include calling on Prescribing Health Care Providers to detail Tassigna. “Sales Representative” also includes those who occupy positions titled “Professional Sales Representative,” “Sales Professional,” “Specialty Sales Representative,” “Senior Sales Representative,” “Senior Health Care Representative,” “Professional Representative,” “Health Care Representative”, “Medical Service Representative”, and “Medical Sales Representative” or any other titles used by You and any of its divisions to describe a role fitting the above job description.

Call Notes: all database entries in any Call Notes database(s) reflecting contacts with Prescribing Health Care Provider(s) relating to Tassigna.

Remuneration: any direct payments made to the recipient of monetary value greater than \$100 in cash or in kind, but specifically excludes samples, discounts and rebates, in-kind items for charity care, educational materials intended for patients, medical devices loaned for clinical trials, and warranty services.

Relevant Time Period: from Tassigna’s initial U.S. approval in October 2007 through the later of (1) the date of the last prescription of Tassigna to Plaintiff, as set forth in the PFS, or (2) the date of the earliest treatment for the condition for which Plaintiff is seeking damages as set forth in the PFS.

Consulting Relationship: any Prescribing Health Care Provider's service to You as a Clinical Investigator or consultant.

Document: any writing or record of every type that is in your possession, custody, or control, including but not limited to written documents, e-mails, cassettes, videotapes, photographs, charts, computer discs or tapes, x-rays, drawings, graphs, phonorecords, nonidentical copies and other data compilations that are reasonably accessible from which information can be obtained and, if necessary, translated by the plaintiff into reasonably usable form. In responding to the document demands in this fact sheet, NPC will not search or produce documents from any sales force custodial files. Any such production from sales force custodial files will be deferred until the identification of a discovery pool, or the commencement of case-specific discovery in a particular case, at which time the parties will meet and confer regarding the scope and timing of any production.

I. CASE INFORMATION

This DFS pertains to the following Plaintiff: _____

Case Number: _____

Date this DFS was completed: _____

Date this DFS was supplemented: _____

II. COMMUNICATIONS WITH PRESCRIBING HEALTH CARE PROVIDER(S)

For each Prescribing Health Care Provider, please provide the following information:

A. Sales Calls

1. If any Sales Representative called on or communicated with Plaintiff's Prescribing Health Care Provider(s) regarding Tassigna, please provide the following information for each during the Relevant Time Period:

a. Name of Sales Representative	b. Title	c. Relationship to Defendant, (including whether current or former employee)	e. Name of Health Care Provider	g. Dates of contacts

- For each individual identified in Section II, and in addition to and without waiving any of Plaintiffs’ current or future requests relating to production of databases containing such materials, please identify and produce complete Call Notes for each contact identified in the chart above with each Prescribing Health Care Provider. The parties will meet and confer regarding the format for production.

B. Marketing Information

- Produce any Marketing Information that You identified in completing this fact sheet as being shown or provided to Plaintiff’s Prescribing Health Care Provider, unless it has already been produced to Plaintiff. NPC agrees to supplement this production if additional Marketing Information is identified at a later date.

C. Medical Inquiries

- Have You ever received from the Plaintiff’s Prescribing Health Care Provider(s) a medical inquiry regarding Tassigna?

Yes _____

No _____

2. Identify and produce all medical inquiries identified in this Section and all responses.

D. Dear Doctor/Dear Health Care Provider Letters

1. Please identify by Bates Number evidence you have that demonstrate that any correspondence to plaintiff's prescribing physician(s) regarding cardiovascular events was sent.
2. For each such letter and/or document identified, provide the following information:

a. Sender	b. Method of transmission	c. Letter or document date	d. Recipient

III. CONSULTING AND OTHER RELATIONSHIPS WITH PRESCRIBING HEALTH CARE PROVIDERS

For each of Plaintiff's Prescribing Health Care Provider(s), please answer the following:

- A. If the Prescribing Health Care Provider has had a Consulting Relationship with You regarding Tassigna, please provide the following for each:

1. Prescribing Health Care Provider	2. Date(s) consulted, retained, and/or Remuneration provided	3. Nature of affiliation	4. Remuneration

B. Identify and describe any remuneration provided by You to Plaintiff's Prescribing Health Care Providers and, include a description of what was provided, the date it was provided, and the estimated value of same.

a. Description of Remuneration	b. Date provided	c. Estimated value

IV. PRESCRIBING HEALTH CARE PROVIDER PRACTICES AND CLINICAL TRIAL INFORMATION

A. Identify and produce documents or information that track the prescribing practices of Plaintiff's Prescribing Healthcare Provider(s) with respect to Tassigna during the Relevant Time Period. Plaintiffs shall agree to any terms of use required by any third-party vendors that maintain this data, and the data will only be provided to Plaintiffs upon receipt of such agreement.

B. Clinical Trials

1. Were any of Plaintiff's Prescribing Health Care Providers involved in any clinical trials sponsored by You related to Tassigna?

Yes _____

No _____

2. If "Yes," identify and produce the final Investigator Protocol related to any such trial(s).

V. PLAINTIFF'S MEDICAL CONDITION

A. Contact Regarding Plaintiff

1. Have You been contacted by Plaintiff or anyone acting on behalf of Plaintiff (other than Plaintiff's counsel), concerning Plaintiff's use of Tassigna?

Yes _____

No _____

2. If "Yes," identify and produce all documents reflecting any contacts identified in V.A.1.

B. Novartis Initiated Contact

1. Other than in connection with any adverse event report, have You initiated contact with the Plaintiff's Prescribing Health Care Provider(s) or Plaintiff concerning Plaintiff's injuries?

Yes _____

No _____

2. If "Yes," identify and produce all documents reflecting any contacts identified in V.B.1.

C. Identify and produce documents from the Argus database regarding Plaintiff's use of Tassigna.

CERTIFICATION

The foregoing answers were prepared with the assistance of a number of individuals, including counsel, upon whose advice and information I relied. I declare under penalty of perjury that all of the information provided in this Defendant Fact Sheet is true and correct to the best of my knowledge.

(Signature)

Name (Printed)

Dated