

**SUPERIOR COURT OF NEW JERSEY  
LAW DIVISION: BERGEN COUNTY**

**IN RE YAZ®, YASMIN®, OCELLA®  
LITIGATION**

**CASE NO. 287**

**CIVIL ACTION**

*This Document Relates to All Actions*

**DEFENDANTS' FACT SHEET**

For each case, the Defendants must complete this Defendants' Fact Sheet ("DFS") and identify or provide documents and/or data relating to each Plaintiff responsive to the question set forth below to the best of Defendants' knowledge. In completing this DFS, you are under oath and must provide information that is true and correct to the best of your knowledge. If you cannot recall all of the details requested, please provide as much information as you can. The DFS shall be completed in accordance with the requirements and guidelines set forth in the applicable Case Management Order.

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

This DFS must be completed and served on all counsel representing a Plaintiff in the action identified in Section I below. This DFS must be answered and served by the date established by the Court in the Case Management Order implementing this DFS.

As used herein, the term "Documents" shall have the broadest possible meaning and interpretation and shall include, without limitation, any written, printed, typed, photostatic, photographed, recorded, computer generated, computer-stored, or otherwise maintained or reproduced communication or representation, any data compilation in any form, whether comprised of letters, words, numbers, pictures, sounds, bytes, emails, electronic signals or impulses, electronic data, active files, deleted files, file fragments, or any combination thereof including, without limitation, all memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, projections, estimates, working papers, accounts, analytical records, reports and/or summaries of investigations, opinions or reports of consultants, opinions or reports of experts, opinions or reports of accountants, other reports, trade letters, press releases, comparisons, books, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, forecasts, drawings, diagrams, instructions, minutes of meetings or communications of any type, including inter- and intra-office communications, questionnaires, surveys, charts, graphs, photographs, films, tapes, discs, data cells, drums, printouts, all other compiled data which can be obtained (translated, if necessary, through intermediary or other devices into usable forms), documents maintained on, stored in or generated on any electronic transfer or storage system, any primary versions, drafts or revisions of any of the foregoing, and other writings or documents of whatever description or kind, whether produced or authorized by or on behalf of you or anyone else, and shall include all non-identical copies and drafts of any of the foregoing now in the possession, custody or control of you, or your present directors, officers, counsel, agents, employees, partners, consultants, principals, and/or persons acting on your behalf Defendants are not required to identify or produce any pleading filed in litigation relating to Yaz®, Yasmin® or Ocella® or medical records produced in Plaintiff's individual case.

As used herein, the terms "you," "your" or "yours" means all Defendants and any officers, agents, attorneys, employees, representatives or others acting on their behalf.

As used herein, the phrase "provided" means sold, distributed, shipped, delivered or otherwise placed into the stream of commerce.

As used herein, the term "communication" and/or "correspondence" shall mean and refer to any oral, written or electronic transmission of information, including, without limitation, meetings, discussions, conversations, telephone calls, memoranda, letters, e-mails, text messages, conferences, or seminars or any other exchange of information between Defendants or between you and any other person or entity.

Nothing in this DFS shall require Defendants to produce voice mail, instant messages, text messages, or be construed contrary to the requirements of the Case Management Order No. 2, governing the preservation of documents and electronically stored information, or any other Order, in this action.

As used herein, the phrase "Dispensing/Prescribing Health Care Provider" means each of Plaintiff's physicians, medical providers, practices, clinics, persons or entities who prescribed or dispensed Yaz® / Yasmin® / Ocella® to Plaintiff as identified with particularity in the Plaintiff Fact Sheet ("PFS").

As used herein, the phrase "anyone in their practice" means all employees of the clinic, practice, or group including, but not limited to, nurse practitioners, and/or other physicians that practice in the same office, group, or clinic with Plaintiff's Dispensing/Prescribing Health Care Provider.

As used herein, the phrase "Promotional Items" means any and all promotion items, marketing devices, freebies, merchandise, handouts, meals, or any other items related to Yaz® / Yasmin® / Ocella® including but not limited to physical items marked with the Yaz® / Yasmin® / Ocella® trademark such as anatomical models, notepads, post-it-notes, pens, flashlights, other day-to-day office supplies of any type, models for patient demonstration, diagnostic tools and aids, medical assessment and dosage calculators, pharmacy and pharmacist tools, patient compliance tools, custom medical calculators and software, branded apparel (such as but not limited to shirts, hats, etc), leather portfolios, prescription pads, picture frames, letter openers, clipboards, water bottles, coffee mugs/cups, pocket/pen lights, key chains, badge-holders, bags, travel accessories, other "freebies" provided to Dispensing/Prescribing Health Care Providers (this list is not meant to be exhaustive). Promotional Items shall mean and include any and all cross-promotional materials related to Yaz® / Yasmin® / Ocella® jointly with other products or advertising campaigns.

As used herein, the term "identify" or "identity" with respect to persons, means to give, to the extent known, the person's full name, and as to former employees or third-parties, their present or last known address.

As used herein, the term "person" means natural person, as well as corporate and/or governmental entity.

As used herein, the terms "relating to," "relate to," "referring to," "refer to," "reflecting," "reflect," "concerning," or "concern" shall mean evidencing, regarding, concerning, discussing, embodying, describing, summarizing, containing, constituting, showing, mentioning, reflecting, pertaining to, dealing with, relating to, referring to in any way or manner, or in any way logically or factually, connecting with the matter described in that paragraph of these demands, including documents attached to or used in the preparation of or concerning the preparation of the documents.

As used herein, the term "possession, custody or control" shall mean and refer to any documents in your possession, custody or control. A document is deemed to be in your "possession, custody or control" if it is in your physical custody or if it is in the physical custody of another person or entity, and you: (a) own such document in whole or in part; or (b) have a legal right by contract, statute or otherwise to use, inspect, examine or copy such document on any terms. If Defendant is aware of documents responsive to a question/request in the DFS that are in the possession of a non-party but do not have a legal right to obtain the documents from the non-party, Defendant will identify the non-party and the nature of the documents in the response to the associated question/request in the DFS. Defendant Bayer Healthcare Pharmaceuticals, Inc. ("BHCP") shall produce information responsive to this DFS in the possession, custody and control of Intendis, Inc.

As used herein, the terms "Yaz," "Yasmin" or "Ocella" mean birth control drugs containing drospirenone, and any predecessor or non-final derivation of the drug that later became "YAZ®," "Yasmin®" or "Ocella®."

Unless otherwise indicated, the "relevant period" for the information sought is January 1, 1990 to the present.

Nothing herein prohibits the Defendant from withholding any materials or information protected by a claim of privilege. A privilege log shall be provided only to the extent of listing (i) any document responsive to this fact sheet that (ii) refers to the Plaintiff and/or the Dispensing/Prescribing Health Care Provider, and (iii) is withheld from production or from which any information has been redacted on a claim of attorney-client privilege or attorney work product protection. The privilege log shall not include documents and communications created in connection with or in the course of the defense of the action to which this DFS relates, but shall include all business documents and communications, including those created after the commencement of the action to which this DFS relates. As to any such document, specify the privilege or work product protection(s) you claim, and provide the following information: (a) the nature of the document (e.g., letter, memorandum, contract, etc.) and a description of its subject matter; (b) the author or sender of the document; (c) the recipient(s) of the document; (d) the date that the document was authored, sent and received; and (e) the basis for your privilege claim. If the claimed privilege or work product protection applies only to a particular phrase, sentence, paragraph, or section of a responsive document, the entire document should be produced with the allegedly protected portion redacted and a legend indicating that the withheld portion is a subject of a specified privilege or protection.

If you are aware that any document that was, or might have been, responsive to any sections of this DFS which concern or relate to Plaintiff or Plaintiff's Dispensing/Prescribing Health Care Provider was destroyed, erased, surrendered or otherwise removed from your possession, custody or control, at any time, provide, to the maximum extent possible, the following information: (a) the nature of the document (e.g., letter, memorandum, contract, etc.) and a description of its subject matter; (b) the author or sender of the document; (c) the recipient(s) of the document; (d) the date that the document was authored, sent and received; (e) the circumstances surrounding the removal of the document from your custody, possession or control; and (f) the identity of the person(s) having knowledge of such removal from your custody, possession or control.

I.

**CASE INFORMATION**

This DFS pertains to the following case:

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

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

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

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

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

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

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

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

B: \_\_\_\_\_  
(Name)

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

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

**II. CONTACTS WITH DISPENSING/DISPENSING/PRESCRIBING HEALTH CARE PROVIDER**

For each Dispensing/Prescribing Health Care Provider identified in the PFS, please state the following:

**A. Dear Doctor Letters:**

1. Please identify the "Dear Doctor" or "Dear Heath Care Provider" letter that you contend was actually sent to the Plaintiffs' Dispensing/Prescribing Health Care Provider concerning Yaz® / Yasmin® /Ocella®.

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*NOTE: Please attach hereto, to the extent available, a copy of each letter and the envelope or fax cover sheet in which it was allegedly sent to Plaintiff's Dispensing/Prescribing Health Care Provider.*

2. For each "Dear Doctor" or "Dear Healthcare Provider" letter identified in Section II(A)(1) that you contend was actually sent to Plaintiff's Dispensing/Prescribing Health Care Provider, please state the date that each "Dear Doctor" or "Dear Heath Care Provider" letter was actually sent to Plaintiff's Dispensing/Prescribing Health Care Provider and the person to whom each letter was sent and the manner in which it was sent

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3. For each "Dear Doctor" or "Dear Heath Care Provider" letter identified in Section II(A)(1) that you contend was actually sent to Plaintiff's Dispensing/Prescribing Health Care Provider, please provide or identify by Bates number any and all lists or databases which you contend demonstrates that these letters were actually sent and provide any proofs available of receipt of said letter(s).

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4. Please identify the person or persons who provided information responsive to Section \_\_\_\_ or any of its subparts.

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**B. Other Contacts**

- For each Dispensing/Prescribing Health Care Provider identified in the PFS, please produce or identify all contacts and communications between the Dispensing/Prescribing Health Care Provider and Defendants' Sales Representatives that relate to Yaz, Yasmin, Ocella, Premenstrual Syndrome ("PMS"), Premenstrual Dysphoric Disorder ("PMDD"), or acne.

Plaintiff's Dispensing/Prescribing Health Care Provider	Name and, if no longer employed by defendant, last known address and telephone number of Defendants' Sales Representative	Current employment status of Sales Representative	Date Range of Contacts

- For each Sales Representative or detail person that had contact with each Dispensing/Prescribing Healthcare Providers listed in the PFS regarding Yaz, Yasmin, Ocella Premenstrual Disorder ("PMS"), Premenstrual Dysphoric Disorder ("PMDD"), or acne. please provide the following information:

Plaintiffs Prescribing / Dispensing Health care Provider	Name of Sales Rep / Detail Person	Territory (ies) Covered	Date of Hire / Date Last Employed	Supervising District Manager(s) and, if no longer employed by defendant, last known address and telephone number	Supervising Field Sales Director current (or last known) and, if no longer employed by defendant, last known address and telephone number

3. For each Dispensing/Prescribing Health Care Provider, please state whether Defendants or their representatives ever provided him/her (or anyone in their practice) Yaz® / Yasmin® / Ocella® samples. If the answer is "yes," please state:
- (a) The number of sample packets provided and the dosages provided for each product;
  - (b) The dates that they were shipped and/or provided;
  - (c) The lot numbers for the samples provided on each date identified;
  - (d) The identity of the person or persons who provided the Samples;
  - (e) With regard to the region or territory, serviced or covered by any such representative, identify the allocation, or total amount and number of sample packets provided with regard to (a) – (c) above and whether or not additional samples were provided and the time frame during which such additional items were provided for said market.
4. For each Dispensing/Prescribing Health Care Provider, please state whether Defendants or their representatives ever provided him/her (or anyone in their practice) with "Promotional Items" (if available, a physical sample of each Promotional Item will be produced to Plaintiffs' Lead Counsel). If the answer is "yes," please state:
- (a) A description of each Promotional Item provided;
  - (b) The dates that each type of Promotional Item was delivered, shipped and/ or provided;
  - (c) The total quantity of each such Promotional Item delivered to each Dispensing/Prescribing Health Care Provider;
  - (d) The identity of the person or persons who provided the Promotional Item; and
  - (e) The fair market value of each such Promotional Item.
  - (f) With regard to the foregoing, please identify any and all instances where products, including but not limited to Yaz® / Yasmin® / Ocella® were promoted, marketed, advertised or offered, in conjunction with other products, or product lines and cross marketed. This includes, for example any gestational calendars, or other similar materials, that offered, marketed, promoted or advertised multiple items with modified or limited warnings. (i.e. Angelia, Yaz & Mirena).

5. For each Dispensing/Prescribing Health Care Provider, please produce any data or documents that identify whether Defendants or their representatives ever provided him/her (or anyone in their practice) with any type of documentation (including published studies or journal articles) relating in any way to the safety, efficacy, benefits, risks or on- or off-label use of Yaz® / Yasmin® / Ocella®, including, to the extent available:
- (a) A description of each document provided;
  - (b) The dates that the document was mailed and/or provided; and,
  - (c) The identity of the person or persons who provided the documentation;
  - (d) A copy of any cover letters sent to Plaintiff's Dispensing/Prescribing Physician or anyone in their practice with the material.
6. For each Sales Representative or detail person identified in Section II(B)(2) above, produce a copy of the Sales Representative's custodial file relating to Yaz®, Yasmin® or Ocella® no later than 60 days in advance of the first deposition specific to this action that is noticed by Defendants, including:
- (a) Any and all notes or other documents of that person or persons, including all personal notes, calendar entries, computer entries, that reflects or refers to any communications with any of Plaintiff's Dispensing/Prescribing Health Care Providers.
  - (b) Any and all notes or other documents of that person or persons, including all personal notes, calendar entries, computer entries, backgrounder documents, marketing information or other documents referred to in the sales call notes and other materials that is/ was in their possession concerning Yaz® / Yasmin® / Ocella®.
  - (c) Any and all information including promotional information, that the Sales Representative or detail person distributed to any of Plaintiff's Dispensing/Prescribing Health Care Providers or any provider in the practice.

7. Please identify the person or persons who provided information responsive to Section II or any of its subparts.

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**III. CONSULTING WITH PLAINTIFF'S DISPENSING/PRESCRIBING HEALTH CARE PROVIDER**

- A. If you have ever retained any of the Dispensing/Prescribing Health Care Providers listed in the PFS as a "thought leader," "Key Opinion Leader", a member of a "speaker's bureau," a "clinical investigator," a "consultant" or in any other capacity on the subject of Yaz® / Yasmin® / Ocella®, Premenstrual Syndrome ("PMS"), Premenstrual Dysphoric Disorder (PMDD), or the treatment of acne, please provide the following information:

Name of Plaintiff's Dispensing/Prescribing Health Care Provider who was retained by Defendants	Date(s) he or she was retained	All records of any documents relating Yaz, Yasmin and/Ocella, PMS, PMDD or acne as related to these products provided to Dispensing/Prescribing Health Care Provider by Defendants

- B. For each Dispensing/Prescribing Health Care Provider identified in the PFS (regardless of whether included in Section III(A) above or not), please state how much money you have paid to them, whether for expenses, honoraria, fees, or any other payment, for each calendar year, and produce the 1099s or, if unavailable, other documents or data sufficient to evidence such payments:

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- C. For each Dispensing/Prescribing Health Care Providers identified in Section III(B) above, please identify or provide all consulting agreements and contracts.
- D. For each Dispensing/Prescribing Health Care Providers identified in the PFS, please state whether they ever attended any Defendant-sponsored conferences or events ("Programs") relating to Yaz, Yasmin, Ocella, PMS, PMDD or acne. If your answer is "yes," please state:

Identity of the Dispensing/Prescribing Health Care Provider	Title, location and date of the Program attended	Topic of the Program	All speakers at the Program	Please provide or identify the agenda/brochure for the Program

- E. Have Plaintiff's Dispensing/Prescribing Health Care Providers ever contacted you to request information concerning Yaz® / Yasmin® / Ocella®, its indications, its effects and/or its risks?

\_\_\_\_\_ Yes

\_\_\_\_\_ No

If "Yes," please identify and attach any document that refers to your communication with Plaintiff's Dispensing/Prescribing Health Care Providers and/or any document that was provided to Plaintiff's Dispensing/Prescribing Health Care Providers in response to such request for information.

- F. Please identify the person or persons who provided information responsive to Section III or any of its subparts, giving their name, address, telephone number indicating whether said person is currently an employee of Defendants and/or any of its subsidiaries and the dates of employment.

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IV.

**PLAINTIFF'S DISPENSING/PRESCRIBING HEALTH CARE PROVIDER'S DISPENSING/PRESCRIBING PRACTICES**

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

- A. Do you have or have you had access to any database or information which purports to track the dispensing/prescribing practices of any Dispensing/Prescribing Health Care Providers listed in the PFS with respect to Yaz® / Yasmin® / Ocella® or any other combination contraceptive drug (including, but not limited to the product(s) prescribed, the number or prescriptions, the number of refills and the time frame when these products were prescribed or refilled).

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

If your answer is "Yes," please produce or identify the database or document that captures that information:

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- B. Please identify the person or persons who provided information responsive to Section IV or any of its subparts.

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V.

**PLAINTIFF'S MEDICAL CONDITION**

A. Other than in connection with any adverse event report, have you initiated contact with any of Plaintiff's physicians concerning Plaintiff's injuries?

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

B. Other than in connection with any adverse event report, have you been contacted by Plaintiff, any of her physicians, or anyone on behalf of Plaintiff concerning Plaintiff (other than counsel for plaintiff)?

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

C. If your answer to A or B above is "Yes," please state the name, address and telephone number of these individuals.

Name	Address	Phone

D. Please produce any non-privileged documents that reflect any communication between Plaintiff, any of her physicians, or anyone on behalf of Plaintiff (other than counsel for plaintiff, and you, concerning Plaintiff.

E. Please produce a copy of any MedWatch form which refers or relates to Plaintiff, including back-up documentation concerning Plaintiff and any evaluation or investigation you did concerning the Plaintiff.

F. Please identify the person or persons who provided information responsive to Section V or any of its subparts.

\_\_\_\_\_  
\_\_\_\_\_

**VI. ADVERTISING**

1. Aside from national advertising (i.e., advertising buys that were not directed in any way to specific regions), did you advertise Yaz® / Yasmin® / Ocella® in the Media Market of where Plaintiff resided at, or within 6 months of, the time she used Yaz® / Yasmin® / Ocella®?

Yes                       No

2. If your answer is "yes," please provide the following information:

Identity of the Advertisement	Nature of media (print or television)	Identify the media outlet	Dates that advertisements ran

Please provide or identify true and accurate copies of any advertisement identified above.

3. Aside from national advertising, did you advertise Yaz® / Yasmin® / Ocella® in the Media Market of any of the Dispensing/Prescribing Health Care Providers' office locations listed on the PFS at, or within 6 months of, the time that Plaintiff used Yaz® / Yasmin® / Ocella®?

Yes                       No

4. If your answer to the preceding question is "Yes," please provide the following information:

Identity of the Advertisement	Nature of media (print or television)	Identify the media outlet	Dates that advertisements ran; Prescriber/Dispenser on PFS within 100 miles

Please provide or identify true and accurate copies of any advertisement identified above.

5. Was the Plaintiff registered with any program owned, operated or controlled by Defendant whereby Plaintiff received electronic communications concerning Yaz® / Yasmin® / Ocella®? If your answer is yes, identify or produce documents describing such program and reflecting any communications with the Plaintiff.

**VII. THIRD PARTIES**

- A. Name each and every party whom you believe is a necessary and proper party to this litigation.

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- B. Name each and every party whom you believe caused or contributed to the injuries or damages of Plaintiff.

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## VIII. DOCUMENTS

- A. To the extent you have not already done so, please produce a copy of all documents and things in your possession, custody and control that fall into the categories listed below.
1. Any non-privileged document which relates to or refers to Plaintiff other than documents received or produced in discovery in this matter, and subject to the limitations and exceptions described in this DFS. .
  2. Any document sent to or received from any of Plaintiff's Dispensing/Prescribing Health Care Providers relating to Yaz® / Yasmin® / Ocella®, subject to the limitations and exceptions described in this DFS.
  3. Any document reflecting any actual communication between you and Plaintiff's Dispensing/Prescribing Health Care Providers concerning the topics identified in Section III(F), subject to the limitations and exceptions described in this DFS.
  4. Any documents reflecting any contacts or actual communications between you and any of Plaintiff's Dispensing/Prescribing Health Care Providers regarding Yaz® / Yasmin® / Ocella®, subject to the limitations and exceptions described in this DFS.
  5. Any document which reflects or purports to describe the Dispensing/Prescribing practices of any of Plaintiff's Dispensing/Prescribing Health Care Providers relating to Yaz®, Yasmin®, Ocella®, PMDD, or acne, subject to the approval or agreement of the owner of the prescribing data to release the data.
  6. Any and all documents requested or referred to in Sections I-VII, above.

**CERTIFICATION**

I am authorized to make this Certification on behalf of \_\_\_\_\_. The information provided in the foregoing Defendant Fact Sheet has been compiled by employees and legal counsel for \_\_\_\_\_. Although I do not have personal knowledge of all of the information set forth therein, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge, understanding and belief, formed after due diligence and reasonable inquiry.

\_\_\_\_\_  
Signature

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

\_\_\_\_\_  
Date

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