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WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

IN RE ACTOS (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

This Document Applies to:  
All Cases

MDL No. 6:11-md-2299

JUDGE DOHERTY

MAGISTRATE JUDGE HANNA

**CASE MANAGEMENT ORDER:**  
**DEFENDANT FACT SHEETS**

**I. Scope of Order**

This Agreed Order applies to claims based on alleged ingestion of Actos®, ACTOplus Met®, ACTOplus Met XR®, Duetact®, or pioglitazone (“Actos”) that (i) currently are pending in MDL No. 2299, (ii) currently are pending in the Western District of Louisiana and are related to MDL No. 2299, or (iii) subsequent to the date of this Order are filed in, removed to, or transferred to this Court (collectively, “MDL Proceedings”). This Order is binding on all parties and their counsel in all cases currently pending or subsequently made part of these proceedings and shall govern each case in the proceedings.

**II. Defendant Fact Sheets**

The Court hereby approves, with the consent of the parties, the use of the Defendant Fact Sheet (“DFS”) attached as **Exhibit A**.

A. The parties have agreed upon a DFS. *See* Exhibit A. Takeda Pharmaceuticals U.S.A., Inc., Takeda Pharmaceuticals U.S.A., Inc., and Takeda Global Research & Development Center, Inc. (collectively, “Takeda”) shall collectively serve upon Plaintiffs’ Liaison Counsel and each Plaintiff’s counsel of record (as identified in the PFS) an electronic copy of a complete DFS negotiated by the parties. Eli Lilly & Company (“Eli Lilly”) shall provide a DFS only if the

Plaintiff alleges use of Actos® beginning on or before December 31, 2007. For cases in which Plaintiff alleges use of Actos® solely between January 1, 2008 and December 31, 2008, Eli Lilly shall provide the names of Eli Lilly sales representatives who called on Plaintiff's prescribing physician(s) and the dates of those calls.

B. In connection with negotiations regarding the DFS, which Defendants Takeda Pharmaceuticals USA, Inc., Takeda Pharmaceuticals America, Inc., Takeda Global Research & Development Center, Inc., and, if applicable, Eli Lilly, shall serve on plaintiffs pursuant to the terms of the applicable case management order, Counsel for the Takeda and Eli Lilly Defendants ("Counsel") have conducted an investigation to determine sources of information sought in the requests set forth in the DFS. As a result of this investigation, Counsel represent to Plaintiffs and this Court that only the aforementioned Defendants, Takeda Pharmaceuticals USA, Inc., Takeda Pharmaceuticals America, Inc., Takeda Global Research and Development Center, Inc., and Eli Lilly, systematically collect and record information sought in the DFS. Though Takeda Pharmaceutical Company Limited is involved in the maintenance of a database containing adverse event reporting information, such information is duplicative of information accessible by Takeda Global Research & Development Center, Inc. Other Takeda Defendants, such as Takeda Pharmaceuticals LLC, Takeda Pharmaceuticals International, Inc., and Takeda California, Inc., have no involvement in the sale or marketing of Actos®, or in the tracking and reporting of adverse event reports, and do not systematically collect and record information sought in the DFS. Plaintiffs shall be granted the opportunity to refute Defendants' representations if Plaintiffs believe that discovery shows the involvement of Takeda Pharmaceuticals LLC, Takeda Pharmaceuticals International, Inc., Takeda Pharmaceutical Company Limited, and/or Takeda California, Inc. in a way that will require Defendants to produce a DFS for one or more of these

entities. To refute Defendants' representations and initiate Defendants' obligations to produce a DFS for any additional entities, Plaintiffs shall first meet and confer with Defendants regarding whether a DFS is required from these entities. If no agreement is reached through the meet-and-confer process, the parties shall seek the Court's guidance before Plaintiffs commence any such discovery.

### **III. Production of Defendant Fact Sheets and Challenges to Completeness**

A. For cases in which a PFS is served after the date of this Order, Takeda and, if applicable, Eli Lilly shall provide a complete DFS within 90 days after receipt of a PFS that meets the triggering requirements established in Section B. below. The DFS will include all available documents responsive to the requests within the DFS, including Actos®-related records for Plaintiffs' Treating Health Care Providers, as defined in the DFS.

B. For a PFS to trigger Defendants' DFS obligations, Plaintiff must:

1. Answer all applicable questions **in Sections I (A), II (A-F), III, IV, and V (A and B) of the PFS<sup>1</sup>**;
2. Include a signed Declaration and Certification (found at Sections X and XII of the PFS);
3. Provide duly executed record release Authorization(s); **and**
4. Designate treating health care provider(s) by completing a "Plaintiff's Designation of Treating Physicians for Defendant Fact Sheets" form.

C. If Defendants contend that any PFS is not substantially complete in that the requisite triggering information set forth in Section B. above is incomplete, they shall notify

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<sup>1</sup> Non-substantive omissions, such as the inadvertent failure to provide a zip code, phone number, or other non-substantive information, shall not form the basis of a claim that a Plaintiff's PFS is not substantially complete so that a DFS is not required.

Plaintiff's individual counsel by E-Mail within thirty (30) days of any alleged deficiencies. Failure to notify Plaintiff's counsel within the thirty (30) days shall mean Defendants will provide a complete DFS within 90 days after receipt of the PFS. Upon receipt of an E-Mail alleging deficiencies, Plaintiff shall have twenty-one (21) days to respond or otherwise contest the deficiencies alleged in the E-Mail. If Defendants allege a PFS deficiency that pertains to the triggering requirements established in Section III.B.1. or 2. above, if Plaintiff has not contested the deficiency, Plaintiff shall respond by producing a supplemental PFS. If Defendants allege a PFS deficiency that pertains to the documentation triggering requirements established in Section III.B.3. or 4. above, if Plaintiff has not contested the deficiency, Plaintiff shall respond by producing the documentation necessary to meet the triggering requirements. If the parties cannot reach agreement through this meet-and-confer process, the matter may be presented to the Court for resolution.

D. For cases in which a PFS was served on or prior to the date of this Order, defendants shall have 45 days from the date of this Order to notify Plaintiff's counsel of any deficiencies pursuant to Section III.C. and shall have 90 days from the date of this Order to serve a DFS in those cases in which a PFS that meets the triggering requirements of Section III.B. has been served.

E. If Takeda and, if applicable, Eli Lilly, have not produced a complete DFS to Plaintiff's counsel of record by the deadlines set forth in Sections III. A, C, and D of this Order, Plaintiff's counsel shall send a Notice of Overdue or Deficient Discovery to Defendants' Counsel at [ActosMDL.DFS@nelsonmullins.com](mailto:ActosMDL.DFS@nelsonmullins.com). To the extent service via email is not possible, the Notice of Overdue or Deficient Discovery may be served on Defendants' Counsel by sending via first class or overnight mail addressed to Dell P. Chappell, 1320 Main Street, 17<sup>th</sup> Floor,

Columbia, South Carolina 29201. The Notice shall identify the alleged deficiency and state that Takeda and, if applicable, Eli Lilly have twenty-one (21) days to cure the deficiency or otherwise respond to Plaintiff's Notice. If Plaintiff's counsel has not received a complete DFS by the end of the twenty (21)-day notice period, Plaintiff's counsel may, after meeting and conferring with Defendants' Counsel in good faith, seek relief from the Court.

F. Service of the DFS shall be made as follows:

(a) Upon the individual Plaintiff's counsel of record, electronically *via* email. Electronic service shall be supplemented with service of a CD *via* first class or overnight mail, if requested by counsel.

(b) Upon the Plaintiffs Steering Committee, electronically *via* email to Plaintiffs' Counsel at ActosDFS@weitzlux.com. To the extent service via email is not possible, the DFS may be served on Plaintiffs' Counsel by sending them in electronic format on CD via first class or overnight mail addressed to Jonathan Sedgh, 700 Broadway, New York, NY 10003.

#### **IV. Plaintiff's Designation of Treating Health Care Providers**

A. The DFS defines a Treating Health Care Provider as any physician, medical provider, practice, clinic, person, or entity identified with particularity in the PFS who prescribed and/or dispensed Actos® and up to two (2) additional health care providers who have treated the Plaintiff for their alleged Actos®-related injuries and have been designated by the Plaintiff pursuant to the provisions of Case Management Order: Defendant Fact Sheets. The parties have agreed that these two (2) additional health care providers who have treated the Plaintiff for their alleged Actos®-related injuries shall be designated by using the Plaintiff's Treating Health Care Provider Designation form attached as **Exhibit B**.

B. Plaintiffs shall designate their two (2) additional health care providers who have treated the Plaintiff for their alleged Actos®-related injuries at the time of submitting a PFS. For those cases in which a PFS has already been submitted, Plaintiffs shall make such designations within thirty (30) days from the entry of this order.<sup>2</sup>

**V. Additional Agreements and Obligations of the Parties**

A. DFS responses and documents produced therein shall be considered interrogatory answers and responses to requests for production under the Federal Rules of Civil Procedure, and shall be governed in the same manner and standards applicable to written discovery under the Federal Rules of Civil Procedure. The DFS questions and document requests have been negotiated and agreed to by the parties. All objections to the admissibility of information contained in the DFS are reserved and therefore no objections shall be lodged in the responses to the questions and requests contained in the DFS absent special circumstances. The admissibility of information in responses to the DFS shall be governed by the Federal Rules of Evidence and no objections are waived by virtue of any DFS response.

B. Plaintiffs' use of the DFS is in lieu of interrogatories and other discovery devices that they would otherwise have propounded, without prejudice to the Plaintiffs' right to propound additional discovery as part of any bellwether program, in cases selected for trial, or upon remand of a case to its transferor court. Nothing in the DFS shall be deemed to limit the scope of inquiry at depositions, nor shall anything in the DFS or this Order be construed to limit the ability of Plaintiffs to engage in discovery to the fullest extent allowable by the Federal Rules of Civil Procedure and this Court's Orders once case-specific discovery is initiated. The

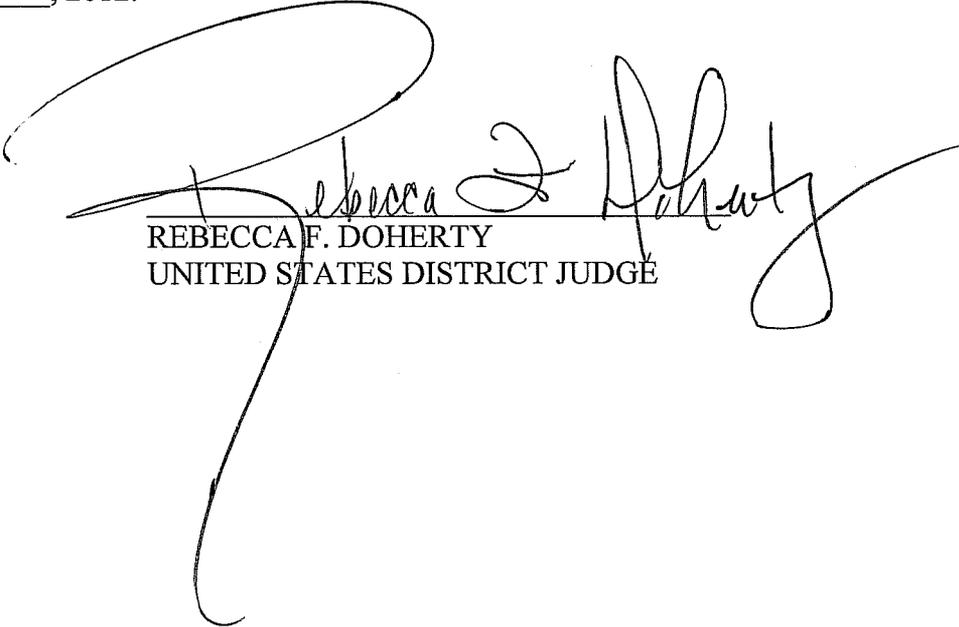
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<sup>2</sup> If a Plaintiff does not intend to designate additional health care providers pursuant to the terms of this Order, the Plaintiff must serve the designation and indicate "none requested" in order to trigger Defendants' DFS obligations.

admissibility of information in the DFS shall be governed by the Federal Rules of Evidence, and no objections are waived by virtue of any DFS response.

C. The parties may agree to an extension of the above time limits for service of a DFS and the Plaintiffs are encouraged to respond reasonably to such requests. If the parties cannot agree on reasonable extensions of time, such party may apply to the Court for such relief.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 13<sup>th</sup> day of November, 2012.

  
REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE