Documents to be Produced

1. All trials, studies, or reports initiated, supported or sponsored by _____ [drug company] relating to _____ [name of drug] , including any conducted outside the United States. This includes those trials, studies, and reports for any New Drug Application (NDA) or Investigational New Drug (IND) application, including any supplemental applications.

2. For those studies published or presented at any major medical meeting(s), a copy of all publications and abstracts and all other materials given to participants.

3. All documents relating to said drug provided to FDA advisory committees;

4. The following documents relating to said drug from FDA approval to the present time:

a. All presentation, training sessions, or materials given to employees or agents who marketed or otherwise promoted said drug , including speakers and consultants;

b. All pamphlets, literature, and other information to be shown or given to physicians by sales representatives, and also provide all related communications;

c. Any other communications provided to healthcare providers regarding the safety and efficacy of said drug , and all related communications;

d. All internal or external presentation or reports based on the marketing plan for said drug , and all communications related to the presentations or reports;

e. All internal or external presentations or reports related to physicians prescribing patterns including data on specialty or prescriber and indications for use, and all communications related to these presentations or reports;

f. All internal or external presentations or reports relating to continuing medical education, and all communications related to these presentations or reports;

g. All internal or external presentations or reports relating to off-label use, and all communications related to these presentations or reports;

h. All documents relating to funding support provided for nonprofit professional medical organizations or consumer/patient organizations; and

i. All marketing department correspondence with nonprofit professional medical organizations or consumer/patient organizations.

Manner of Production

I. This subpoena applies to electronic records as well as physical documents. Format issues shall be handled as provided in the Federal Rules of Civil Procedure.

II. This subpoena applies to all documents in your possession, custody, or control, or any combination thereof.

III. Documents responsive to this subpoena should not be destroyed, modified, removed, transferred, or otherwise made inaccessible.

IV. Each document produced should be produced in a form that renders the document capable of being copied.

V. Documents produced should identify the paragraph or clause that responds to the subpoena.

VI. Documents produced should be produced together with copies of file labels, dividers, or identifying markers with which they were associated when this subpoena was issued. To the extent that documents were not stored with file labels, dividers, or identifying markers, they should be organized into separate folders by subject matter prior to production.

VII. Each folder and box should be numbered, and a description of the contents of each folder and box, including the paragraph or clause of the subpoena to which the documents are responsive, should be provided in an accompanying index.

VIII. If any of the subpoenaed information is available in machine-readable or electronic form (such as on a computer server, hard drive, CD, DVD, memory stick, or computer backup tape), you should consult with James B. Gottstein to determine the appropriate format in which to produce the information. Documents produced in electronic format should be organized, identified, and indexed electronically in a manner comparable to the organizational structure call for in VI & VII above. Documents produced in an electronic format should also be produced in a searchable format.

IX. If any document responsive to this subpoena was, but no longer is, in your possession, custody, or control, you should identify the document (stating its date, author, subject and recipient(s)) and explain the circumstances by which the document ceased to be in your possession, custody, or control.

X. If a date or other descriptive detail set forth in this subpoena referring to a document is inaccurate, but the actual date or other descriptive detail is known to you or is otherwise apparent from the context of the description in this subpoena, you must

produce all documents which would be responsive as if the date or other descriptive detail were correct.

XI. This subpoena is continuing in nature, until further notice, or the underlying matter has been terminated, whichever is earlier, and applies to any newly discovered document. Any document not produced because it has not been located or discovered by the return date should be produced immediately upon location or discovery subsequent thereto.

XII. All documents should be bates-stamped sequentially and produced sequentially.

Representative(s) Who Can Respond to the Following:

With respect to Item No. 1, above, to the extent such information is not contained within the documents brought to the trial, an authorized representative(s) of Janssen who can answer the following questions with respect to the materials required to be produced above. Written response(s) under oath, in lieu of attendance by a Janssen representative will suffice.

A. The name of the author(s) and physician(s) that participated;
B. The number of participants;
C. The date it was initiated, completed, or terminated, if terminated, explaining the reason(s) behind the termination;
D. Summarization of the methodology, findings, and conclusions;
E. The extent to which the marketing department provided funding or other support;
F. The extent to which compensation or benefit(s), monetary or otherwise (including support or assistance in creating manuscripts), was provided to any author, physician, or participant;
G. If not published or presented, an explanation for why the study was not published or presented.

Definitions

1. The term "document" means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to, the following: memoranda, reports, expense reports, books, manuals, instructions, financial reports, working papers, records notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, interoffice and intra-office communications, electronic mail (email), contacts, cables, notations of any type of conversation, telephone call, meetings or other communications, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, massages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alternations, modifications,

revisions, changes, and amendments of any of the foregoing, as well as nay attachments or appendices thereto). The term also means any graphic or oral records or representations or any kind (including without limitation, photographs, charts, graphs, voice mails, microfiche, microfilm, videotape, recordings and motion pictures), electronic and mechanical records or representation of any kind (including, without limitation, tapes, cassettes, disks, computer server files, computer hard drive files, CDs, DVDs, memory sticks, and recording), and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, disk videotape or otherwise. A document bearing any notation not a part of the original text is to be considered a separate document. A draft or non-identical copy is separate document within the meaning of this term.

2. The term "documents in your possession, custody, or control" means (a) documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, or representatives acting on your behalf; (b) documents that you have legal right to obtain, that you have a right to copy, or to which you have access; and (c) documents that you have placed in the temporary possession, custody, or control of any third party.

3. The term "communication" means each manner or means of disclosure or exchange or information, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether face-to-face, in a meeting, by telephone, mail, telexes, discussions, releases, person delivery, or otherwise.

4. The terms "and" and "or" shall be construed broadly and either conjunctively or disjunctively to bring within the scope of the request any information which might otherwise be construed to by outside its scope. The singular includes plural number, and vice versa. The masculine includes the feminine and neuter genders.

5. The terms "person" or persons" means natural persons, firms, partnerships, associations, corporations, subsidiaries, divisions, departments, joint ventures, proprietorships, syndicates, or other legal, business or government entities, and all subsidiaries, affiliates, divisions, departments, branches, and other units thereof.

6. The terms "referring" or "relating," with respect to any given subject, means anything that constitutes, contains embodies, reflects, states, refers to, deals with, or is in any manner whatsoever pertinent to that subject.