#### INTERIM MONITOR AGREEMENT

This Interim Monitor Agreement ("Monitor Agreement") entered into this 15<sup>th</sup> day of June, 2005, among Francis J. Civille, Novartis AG and Sandoz Inc., (where "Respondents" as used herein means Novartis AG and Sandoz Inc. individually and collectively), provides as follows:

WHEREAS, the United States Federal Trade Commission (the "Commission"), in In the Matter of Novartis AG, has accepted or will shortly accept for public comment an Agreement Containing Consent Order, incorporating a Decision and Order (the "Order"), which, among other things, requires Respondents to divest or transfer certain defined assets and, to ensure that Respondents comply with their obligations under the Order, provides for the appointment of an Interim Monitor:

WHEREAS, the Commission may appoint Francis J. Civille as such monitor (the "Interim Monitor") pursuant to the Order to monitor Respondents' compliance with the terms of the Order and with the Remedial Agreement referenced in the Order, and to monitor the efforts of the Commission-approved Acquirer (as defined in the Order) to obtain all necessary FDA approvals, as applicable, and Francis J. Civille has consented to such appointment;

WHEREAS, the Order further provides or will provide that Respondents shall execute a Monitor Agreement, subject to the prior approval of the Commission, conferring all the rights, powers and authority necessary to permit the Interim Monitor to carry out such duties and responsibilities pursuant to the Order;

WHEREAS, this Monitor Agreement, although executed by the Interim Monitor and Novartis AG and Sandoz Inc., is not effective for any purpose, including but not limited to imposing rights and responsibilities on Respondents or the Interim Monitor under the Order, until it has been approved by the Commission; and

WHEREAS, the parties to this Monitor Agreement intend to be legally bound;

NOW, THEREFORE, the parties agree as follows:

- 1. Capitalized terms used herein and not specifically defined herein shall have the respective definitions given to them in the Order. The term "Monitored Assets" means the Desipramine Assets, the Orphenadrine Citrate ER Assets and the Rifampin Assets.
- 2. The Interim Monitor shall have all of the powers and responsibilities conferred upon the Interim Monitor by the Order, including but not limited to:
  - a. supervising the transfer of the Monitored Assets, including Product Registrations, Product Intellectual Property, Product Manufacturing Technology and Confidential Business Information to the Commission-approved Acquirer; and
  - b. supervising the performance of any transition services, including Contract Manufacture, required by the Order.

3. Respondents hereby agree that they will fully and promptly comply with all terms of the Order requiring them to confer all rights, powers, authority and privileges upon the Interim Monitor, or to impose upon themselves any duties or obligations with respect to the Interim Monitor, to enable the Interim Monitor to perform the duties and responsibilities of the Interim Monitor thereunder.

## 4. Respondents further agree that:

- a. they will use reasonable best efforts to ensure that Amide Pharmaceutical, Inc. ("Amide") or another Commission-approved Acquirer enters into an agreement with the Interim Monitor governing the facilitation of the Interim Monitor's duties under the Order and the exchange of information between the Commission-approved Acquirer and the Interim Monitor;
- b. no later than ten (10) Business Days after the Commission approves this Monitor Agreement, they will provide the Interim Monitor with the following, as applicable:
  - (1) a copy of the Remedial Agreements (or drafts thereof) relating to the Monitored Assets, including any exhibits, schedules and appendices;
  - offering or information memoranda, or similar documents and information, provided to the Commission-approved Acquirer relating to the sale of the Monitored Assets;
  - (3) copies of correspondence with, and written reports or minutes of meetings of all contacts and discussions with, any Commission-approved Acquirer relating to the Monitored Assets or Remedial Agreements; and
  - (4) an inventory and description of the Monitored Assets, including a complete inventory of any existing FDA approvals and pending FDA approvals for the Products included in the Monitored Assets and identifying the person(s) responsible for taking such actions as are required to maintain or complete such approvals;
- c. they will designate a senior individual as a primary Contact for the Interim Monitor and provide a written list of the principal individuals to be involved in the transitioning of the Monitored Assets to the Commission-approved Acquirer, together with their locations, telephone numbers, electronic mail address (if available), and responsibilities, and will provide the Interim Monitor with written notice of any changes in such personnel occurring thereafter;
- d. they will use their reasonable efforts to provide the Interim Monitor with prompt notification (but not later than such notification is available to other meeting participants) of significant meetings, including date, time and venue, scheduled

after the execution of this Monitor Agreement, relating to the manufacture, registration, regulatory approvals, marketing, sale and divestiture of the Monitored Assets, and such meetings may be attended by the Interim Monitor or his representative, at the Interim Monitor's option or at the request of the Commission or staff of the Commission;

- e. they will provide the Interim Monitor with the minutes, if any, of the abovereferenced meetings as soon as practicable and, in any event, not later than those minutes are available to any employee of the Respondents;
- f. they will provide the Interim Monitor with all correspondence, meeting minutes, telephone summaries, reports, sent to or received from the FDA after the execution of this Monitor Agreement relating to the Monitored Assets, and will provide prompt notice of any and all meetings or communications with the FDA relating to or affecting the Monitored Assets;
- g. they will provide the Interim Monitor with electronic or hard copies, as may be appropriate, of all reports submitted to the Commission pursuant to the Order, simultaneous with the submission of such reports to the Commission;
- h. to the extent not reflected in the reports submitted to the Commission pursuant to the Consent Agreement and the Order, they will provide every (3) months commencing one (1) month after the Consent Agreement is accepted by the Commission for public comment, or as requested by the Interim Monitor, full and detailed electronic or hard copy reports to the Interim Monitor as to all of Respondents' activities and obligations under the Order concerning the Monitored Assets including, without limitation to the extent applicable:
  - (1) all activities concerning the assistance, advice and consultation provided to any Commission-approved Acquirer generally as provided in Paragraphs II, III, and IV of the Order;
  - as applicable, all activities concerned with the manufacture, supply and technology transfer of the Products, including, without limitation, negotiation and operation of supply agreements, actual supply and inventory; and
  - (3) as applicable, all minutes and records of meetings, action plans, and follow-ups to actions plans and meetings, with the Commission-approved Acquirer related to the manufacture, supply, and technology transfer of the Products and, upon request Respondents shall provide the Interim Monitor with any records exchanged at such meetings, or such other records that the Interim Monitor may reasonably require relating to the manufacture, supply, and technology transfer of the Products;

provided however, that, at the time the Order becomes final, the reports described in this paragraph shall be due to the Interim Monitor either as requested by the Interim Monitor or within five (5) Business Days of the date that Respondents file the Respondents' reports with the Commission as required pursuant to Paragraph VII of the Order;

- i. they will comply with the Interim Monitor's reasonable requests for onsite visits of Respondents' facilities (or any contract manufacturer's facility) used to manufacture the Products; and
- j. they will comply with the Interim Monitor's reasonable requests for follow-up discussions or supplementary information concerning any reports provided to or requested by the Interim Monitor pursuant to this Agreement, including, as applicable: meetings and discussions with the principal staff involved in any activities relating to the research, development, manufacture, sale and or divestiture of the Monitored Assets or any Product comprised therein and, further including, actions necessary to maintain all necessary FDA approvals to manufacture and sell any of the Products in the United States and to prevent the destruction, removal, wasting, deterioration or impairment of the Monitored Assets, and will provide the Interim Monitor with access to and hard copies of all other data, records or other information that the Monitor reasonably believes are necessary to the proper discharge of his responsibilities under the Order.
- 5. Respondents shall promptly notify the Interim Monitor of any significant written or oral communication that occurs after the date of this Monitor Agreement between the Commission and Respondents related to the Order or this Monitor Agreement, together with electronic or hard copies (or, in the case of oral communications, summaries), as may be requested by the Interim Monitor, of such communications.
- 6. Respondents agree that to the extent authorized by the Order, the Interim Monitor shall have the authority to employ, at the expense of the Respondents, and with the consent of Respondents, which will not unreasonably be withheld, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities, including but not limited to supervising the transfer of Confidential Business Information.
- 7. The Interim Monitor shall maintain the confidentiality of all information provided to the Interim Monitor by Respondents. Such information shall be used by the Interim Monitor only in connection with the performance of the Interim Monitor's duties pursuant to this Agreement. Such information shall not be disclosed by the Interim Monitor to any third party other than:
  - a. persons employed by, or working with, the Interim Monitor under this Agreement; or
  - b. persons employed at the Commission and working on this matter.

- 8. The Interim Monitor shall maintain a record and inform the Commission of all persons (other than representatives of the Commission) to whom confidential information related to this Agreement has been disclosed.
- 9. Upon termination of the Interim Monitor's duties under this Monitor Agreement, the Interim Monitor shall promptly return, at Respondents' expense to Respondents all material provided to the Interim Monitor by Respondents that is confidential to Respondents and that they are entitled to have returned to them under the Order, and shall destroy any material prepared by the Interim Monitor that contains or reflects any confidential information of Respondents. Nothing herein shall abrogate the Interim Monitor's duty of confidentiality, including the obligation to keep such information confidential for a period of ten (10) years after the termination of this Monitor Agreement;
- 10. The Interim Monitor shall keep confidential for a period of ten (10) years all other aspects of the performance of his duties under this Monitor Agreement and shall not disclose any confidential or proprietary information relating thereto. To the extent that the Interim Monitor wishes to retain any employee, agent, consultant or any other third party to assist the Interim Monitor in accordance with the Order, the Interim Monitor shall ensure that, prior to being retained, such persons execute a confidentiality agreement in a form agreed upon by the Interim Monitor and Respondents.

For the purpose hereof, information shall not be considered confidential or proprietary to the extent that it is or becomes part of the public domain (other than as the result of any action by the Interim Monitor or by any employee, agent, affiliate or consultant of the Interim Monitor), or to the extent that the recipient of such information can demonstrate that such information was already known to the recipient at the time of receipt from a source other than the Interim Monitor, Respondents, or any director, officer, employee, agent, consultant or affiliate of the Interim Monitor or Respondents, when such source is entitled to make such disclosure to such recipient.

- 11. Nothing in this Monitor Agreement shall require Respondents to disclose any material or information that is subject to a legally recognized privilege or that Respondents are prohibited from disclosing by reason of law or an agreement with a third party.
- 12. The Interim Monitor shall not have a fiduciary responsibility to the Respondents, but shall have fiduciary duties to the Commission.
- 13. Each party shall be reasonably available to the other to discuss any questions or issues that either party may have concerning compliance with the Order as it relates to Respondents.
- 14. Respondents will pay the Interim Monitor NON-PUBLIC INFORMATION for all reasonable time spent in the performance of the Interim Monitor's duties including all monitoring activities related to the efforts of the Commission-approved Acquirer of the Monitored Assets, all work in connection with the negotiation and preparation of this

Monitor Agreement, and all reasonable and necessary travel time. Every six months such hourly rates should be reviewed and may be adjusted by agreement with Respondents.

a. In addition, Respondents will pay (i) all out-of-pocket expenses reasonably incurred by the Interim Monitor in the performance of the Interim Monitor's duties, including any auto, train or air travel in the performance of the Interim Monitor's duties, international telephone calls, and (ii) all fees and disbursements reasonably incurred by such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties.

### NON-PUBLIC INFORMATION

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b.

- c. Any expense charged to a credit card incurred in a currency other than U.S. dollars shall be converted into dollars for expense reimbursement purposes at the exchange rate used for said credit card transaction and any ancillary cash expenses for which a credit card is not possible shall be converted at the exchange rate for which said currency was purchased.
- d. The Interim Monitor shall have full and direct responsibility for compliance with all applicable laws, regulations and requirements pertaining to work permits, income and social security taxes, unemployment insurance, worker's compensation, disability insurance, and the like.
- 15. Respondents hereby confirm their obligation to indemnify the Interim Monitor and hold the Interim Monitor harmless in accordance with and to the extent required by the Order. Respondents shall indemnify the Interim Monitor and any subcontractor and their respective agents, partners, principals, officers and employees (the "Indemnified Parties") and hold the Indemnified Parties harmless (regardless of form of action, whether in contract, statutory law, tort or otherwise) against any losses, claims, damages, liabilities or expenses arising out of or in connection with, the performance of the Interim Monitor's duties and obligations including all reasonable fees of counsel and other

reasonable expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the Interim Monitor.

- 16. The Interim Monitor's maximum liability to the Respondents relating to services rendered pursuant to this Agreement (regardless of the form of the action, whether in contract, statutory law, tort, or otherwise) shall be limited to the total sum of the fees paid to the Interim Monitor by Respondents, except to the extent resulting from the misfeasance, gross negligence, willful or wanton acts, or bad faith by the Interim Monitor or any of his subcontractors, agents, partners, principals, officers or employees, in which case the liability is not so limited.
- 17. Respondents agree that the Respondents' obligations to indemnify the Interim Monitor extend to any agreement that is entered between the Interim Monitor and any Commission-approved Acquirer and relates to the Interim Monitor's responsibilities under the Monitor Agreement and/or the Order.
- 18. Upon this Monitor Agreement becoming effective, the Interim Monitor shall be permitted, and Respondents shall be required, to notify all Commission-approved Acquirers of his appointment as Interim Monitor.
- 19. In the event of a disagreement or dispute between Respondents and the Interim Monitor concerning Respondents' obligations under the Order and, in the event that such disagreement or dispute cannot be resolved by the parties, any party may seek the assistance of the responsible individual in the Commission's Compliance Division to resolve the issue. In the case of any disagreement or dispute between Respondents and the Interim Monitor not relating to Respondents' obligations under the Order, and in the event that such disagreement or dispute cannot be resolved by the parties, the parties shall submit the matter to binding arbitration before the American Arbitration Association under its Commercial Arbitration Rules. Binding arbitration shall not be available, however, to resolve any disagreement or dispute concerning the Respondents' obligations pursuant to the Order.
- 20. This agreement shall be subject to the substantive law of the State of New Jersey (regardless of any other jurisdiction's choice of law principles).
- 21. This Monitor Agreement shall terminate no later then the date set forth in Paragraph V.D.3 of the Order or the Commission has appointed a substitute monitor pursuant to the Order, provided however, that the Commission may extend this Monitor Agreement as may be necessary or appropriate to accomplish the purposes of the Order. The confidentiality obligations of this Monitor Agreement shall survive its termination.
- 22. In the event that, during the term of this Monitor Agreement, the Interim Monitor becomes aware that he has or may have a conflict of interest that may affect or could have the appearance of affecting the performance by the Interim Monitor, or persons

employed by, or working with, the Interim Monitor, of any duty under this Monitor Agreement, the Interim Monitor shall promptly inform both Respondents and the Commission of such conflict or potential conflict.

- 23. In the performance of his functions and duties under this Monitor Agreement, the Interim Monitor shall exercise the standard of care and diligence that would be expected of a reasonable person in the conduct of his own business affairs.
- 24. It is understood that the Interim Monitor will be serving under this Interim Monitor Agreement as an independent contractor and that the relationship of employer and employee shall not exist between Interim Monitor and Novartis AG or Sandoz Inc.
- 25. This Agreement is for the sole benefit of the Parties hereto and their permitted assigns and the Commission, and nothing herein express or implied shall give or be construed to give any other person any legal or equitable rights hereunder.
- 26. This Agreement contains the entire agreement between the parties hereto with respect to the matters described herein and replaces any and all prior agreements or understandings, whether written or oral.
- Any notices or other communication required to be given hereunder shall be deemed to have been properly given if sent by mail or fax (with acknowledgment of receipt of such fax having been received), to the applicable party at its address below (or to such other address as to which such party shall hereafter notify the other party):

If to the Interim Monitor, to:

Francis J. Civille 16 Fox Hill Road Califon, New Jersey 07830 Telephone: (908) 439-2441 Facsimile: (908) 439-3834 email: ficiville@aol.com

#### If to Novartis AG:

Novartis AG Lichtstrasse 35 CH-4002 Basel Switzerland

Telephone: 011 41 61 324 2428

Facsimile: 011 41 61 324 3731 (Attention: General Counsel)

## If to Sandoz:

Sandoz Inc. 506 Carnegie Center Suite 400 Princeton, NJ 08540

Telephone: (609) 627-8510

Fax: (609) 627-8684 (Attention: General Counsel)

## If to the Commission:

Federal Trade Commission 601 New Jersey Avenue Washington, DC 20001

Attn.: Arthur Strong, Esq.

Telephone: (202) 326-3478 Facsimile: (202) 326-3396

29. This Monitor Agreement shall not become binding until it has been approved by the Commission and the Order has been accepted for public comment.

# 30. This Monitor Agreement may be signed in counterparts.

IN WITNESS WHEREOF, the parties hereto have executed this Monitor Agreement as of the date first above written.

Francis J. Civille	Novartis AG
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	Joerg Walther Authorized Signatory
	Novartis AG
	Peter Rupprecht Authorized Signatory
	Sandoz Inc.
	Eric Evans Vice President and Chief Binancial Officer

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Sandoz Inc.

Eric Evans

Vice President and Chief Financial Officer