

## ATTACHMENT 2

This Agreement entered into this \_\_\_\_\_ day of December 2000 between FRANCIS J. CIVILLE (the "Monitor Trustee") and NOVARTIS PHARMACEUTICALS CORPORATION (the "Acquirer"), referred to herein collectively as "the parties," provides as follows:

WHEREAS the Federal Trade Commission (the "Commission") has accepted or will shortly accept for Public Comment an *Agreement Containing Consent Orders* ("Consent Agreement") with SmithKline Beecham plc ("SB") and Glaxo Wellcome plc ("GW") (where "Respondents," as used herein, means SB and GW, individually and collectively), that contains an Order to Maintain Assets and a Decision and Order, collectively hereinafter referred to as the "Orders," which provide for, among other things, the appointment of a Monitor Trustee to ensure that Respondents fully perform their obligations with respect to the Approval Assets (as defined in the related Trust Agreement) under the Orders, and, at Respondents' expense, to monitor the efforts of certain of the Acquirers of the Approval Assets to obtain all FDA approvals necessary to manufacture and sell any Product included within the Approval Assets in or into the United States ("Relevant Product(s)") in a diligent manner,

WHEREAS, the Orders further provide that Respondents shall execute a trust agreement ("Trust Agreement"), subject to the prior approval of the Commission, and confer all the rights, authority and powers necessary to permit the Monitor Trustee to monitor the Respondents' compliance with the terms of the Order and certain activities of the Acquirer, as may be determined by the Commission, related to the transfer of the Relevant Products; and

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

NOW, THEREFORE, the parties agree as follows:

1. The Acquirer shall:
  - a. Provide the following to the Monitor Trustee no later than sixty (60) days after the Closing Date:
    - i. the Acquirer's plan to obtain all necessary FDA approvals to manufacture and sell the Relevant Product(s) divested pursuant to the Orders; and
    - ii. the Acquirer's business plan for developing, manufacturing and marketing of the Relevant Product(s) in or into the United States, together with any timetables and projections, including but not limited to, the Acquirer's annual production forecasts and planned activities relating to manufacture with respect to the Relevant Product(s), including any such activities contracted to a third party.
  - b. To the extent the following are prepared in the ordinary course of Acquirer's business,

provide the following to the Monitor Trustee in a timely manner but no less frequently than once per (6) six month period:

- i. reports that include the annual forecasts and actual quarterly sales (in units and dollars) of the Relevant Product(s) and market share performance in the United States against competitive products;
  - ii. reports that discuss the Acquirer's plans or efforts to sell the Relevant Product(s) in or into the United States or that discuss the Acquirer's plans or efforts to obtain all FDA approvals necessary to manufacture the Relevant Product(s) independent of the Respondents;
  - iii. any completed revisions, amendments, or subsequent reports or plans, related to reports or plans previously provided to the Monitor Trustee; and
  - iv. such additional information as the Monitor Trustee, the Commission, or staff of the Commission may reasonably request.
- c. Within ten (10) days of the occurrence of any of the following, notify the Monitor Trustee if:
- i. the Acquirer has determined to abandon its efforts to obtain FDA approvals necessary to manufacture and/or sell the Relevant Product(s);
  - ii. the Acquirer has voluntarily ceased the sale in the United States of the Relevant Product(s) for any time period exceeding sixty (60) days prior to obtaining all necessary FDA approvals to manufacture and sell the Relevant Product(s); or
  - iii. the Acquirer has failed to obtain all necessary FDA approvals to manufacture and sell the Relevant Product(s) in the United States within four (4) years from the date the Commission approves the Divestiture Agreement between the Respondents and the Acquirer.
- d. Provide the Monitor Trustee promptly with a copy of any meeting minutes, action plans, schedules, written reports related to the Acquirer's significant interactions with the Respondents and/or the FDA on matters related to transition support, technology transfer, manufacturing and supply obligations related to the Relevant Products to the extent these are produced in the ordinary course of the Acquirer's business. This shall include any written correspondence or summaries of oral communications with the FDA, if produced in the ordinary course of the Acquirer's business.
- e. At the Monitor Trustee's request, upon reasonable notice and during regular business hours:

- i. arrange meetings or discussions, at a reasonable location designated by the Acquirer, and provide additional information in response to reasonable requests of the Monitor Trustee, relating to the Acquirer's efforts to obtain FDA approvals or manufacture the Relevant Product(s);
  - ii. provide the Monitor Trustee with direct and sufficient access to Acquirer's representative designated for that purpose, to Acquirer's activities, and to any of Acquirer's personnel (who have direct or indirect responsibility for overseeing Acquirer's efforts to manufacture, or obtain the FDA approvals related to the Relevant Product(s)), in order to allow the Monitor Trustee to determine the status of the Acquirer's efforts to obtain FDA approvals; and
  - iii. provide the Monitor Trustee with sufficient access to any records and facilities that relate to the Acquirer's efforts to obtain FDA approvals to manufacture the Relevant Product(s), including, but not limited to, onsite access to the Acquirer's manufacturing facilities.
- f. Provide the Monitor Trustee with timely advanced notification of significant meetings relating to FDA approvals to manufacture and sell the Relevant Product(s), including any meetings with the FDA and FDA inspections of Acquirer's facilities. Such meetings may be attended by the Monitor Trustee or his representative, at the request of the Monitor Trustee, the Commission, or the staff of the Commission.
- g. Deliver all reports and plans as described herein in written hard copy form in a timely manner to:

Francis J. Civile  
44 Brentwood Drive  
East Hanover, New Jersey 07936

and, at the request of the Monitor Trustee or staff of the Commission, a copy to:

Federal Trade Commission  
Attention: David von Nirschl, Esquire  
601 Pennsylvania Avenue, N.W.; S-2115  
Washington, DC 20580  
Facsimile: (202) 326-2655

- h. Cooperate in any respect reasonably required by the Monitor Trustee to allow him to fulfill his obligations as they relate to the Acquirer under the Orders.

2. The Monitor Trustee shall:
  - a. maintain the confidentiality of all information provided to the Monitor Trustee by Acquirer and shall use such information only for the purpose of discharging his obligations as Monitor Trustee and not for any other purpose, including, without limitation, any other business, scientific, technological, or personal purpose. Such information may be disclosed only to:
    - i. persons employed by or working with the Monitor Trustee under this Agreement and the Trust Agreement, or
    - ii. persons employed at the Commission and working on this matter.
  - b. maintain the confidentiality, for a period of five (5) years after the termination of this Agreement, of all other aspects of the performance of his duties under this Agreement and shall not disclose any confidential or proprietary information relating thereto.
  - c. ensure that, if he retains any employee, agent, consultant or other third party to assist him in accordance with the Orders, such persons execute a confidentiality agreement in a form agreed upon by the Monitor Trustee and Acquirer prior to being retained.
  - d. upon the termination of the Monitor Trustee's duties under the Trust Agreement to which this Agreement is an attachment, promptly return to Acquirer all materials provided to the Monitor Trustee by Acquirer and shall destroy any material prepared by the Monitor Trustee that contains or reflects any confidential Acquirer information.
3. For the purposes of this Agreement, 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 Monitor Trustee or by any employee, agent, affiliate or consultant of the Monitor Trustee), 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 Acquirer or any director, officer, employee, agent, consultant or affiliate of Acquirer when such source is entitled to make such disclosure to such recipient.
4. This Agreement and the rights and obligations of the parties hereunder shall in all respects be governed by the substantive Laws of the State of New Jersey, including all matters of construction, validity and performance.

5. Nothing in this Agreement shall require the Acquirer to disclose any material or information that is subject to a legally recognized privilege or that Acquirer are prohibited from disclosing by reason of law or an agreement with a third party.
6. As used in this Agreement, all capitalized terms used herein and not specifically defined herein shall have the respective definitions given to them in the Consent Agreement and the Orders.
7. Except for the provisions of Paragraph 2 of this Agreement, this Agreement shall terminate when the Acquirer obtains FDA approval to manufacture the Relevant Product(s) in or into the United States, within five (5) years of the date of this Agreement, or the Commission has appointed a substitute trustee pursuant to the Orders, whichever occurs earlier, provided, however, that the Commission may extend this Agreement as may be necessary or appropriate to accomplish the purposes of the Orders.

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

MONITOR TRUSTEE

\_\_\_\_\_

NOVARTIS PHARMACEUTICALS  
CORPORATION

By: \_\_\_\_\_

Its: \_\_\_\_\_