



U.S. Department of Justice

Michael J. Sullivan
United States Attorney
District of Massachusetts

Main Reception: (617) 748-3100

John Joseph Moakley United States Courthouse
1 Courthouse Way
Suite 9200
Boston, Massachusetts 02210

October 11, 2005

Henry J. DePippo, Esq.
Nixon Peabody, LLP
Clinton Square
P.O. Box 31051
Rochester, NY 14603-1051

**Re: Side Letter Agreement with Serono S.A., Serono Holding, Inc.,
Ares Trading S.A. and Serono, Inc.**

Dear Mr. DePippo:

This is to confirm that, in exchange for full performance of the Plea Agreement entered into by and among the United States of America, acting through its Department of Justice and the United States Attorney for the District of Massachusetts (collectively referred to as "the United States") and your client, Serono Laboratories, Inc. ("Serono Labs"), a copy of which Plea Agreement is attached hereto as Exhibit One, and in exchange for certain other promises made herein between and among the United States and your clients, Serono Holding, Inc. ("Serono Holding"), Serono, Inc. (a subsidiary of Serono Holding), Serono S.A. (formerly known as Ares-Serono S.A.), and Ares Trading S.A. ("Ares Trading"), (hereafter Serono Holding; Serono, Inc.; Serono S.A.; and Ares Trading are collectively referred to as "Serono"), the United States and Serono hereby agree as follows:

- a. No Criminal Prosecution of Serono S.A.; Serono Holding; Ares Trading and Serono, Inc.

The United States hereby declines prosecution of Serono S.A.; Serono Holding; Ares Trading and Serono, Inc., and the Serono entities listed in Attachment A hereto, for the following:

- (1) conduct by, or attributable to, Serono S.A.; Serono Holding; Ares Trading or Serono, Inc., or any of the Serono entities listed in Attachment A hereto, that falls within the scope of the conspiracies that are charged in the information to which Serono Labs is pleading guilty;

- (2) conduct by, or attributable to, Serono S.A.; Serono Holding; Ares Trading; Serono, Inc.; and the Serono entities listed in Attachment A hereto, falling within the scope of the grand jury investigation by the U.S. Attorney in Massachusetts including (a) offering or paying remuneration (including kickbacks, bribes or rebates) in order to obtain prescriptions of the drug Serostim from doctors; (b) offering or paying remuneration (including kickbacks, bribes or rebates) in order to obtain prescriptions and sales or orders for the drug Serostim from pharmacies, including but not limited to specialty pharmacies, preferred providers and wholesalers; (c) causing or contributing to the billing to the Medicaid programs, the Federal Employees Health Benefit Program, and any Federal health care programs as defined in 42 U.S.C. §1320a-7b(f), for certain prescriptions that were not reasonable or necessary for the diagnosis or treatment of an illness; (d) concealing or failing to disclose events affecting Serono's continued right to payment, having knowledge of the occurrence of such events, with an intent fraudulently to secure such benefit or payment to which Serono was not entitled; and (e) making or causing to be made false representations or statements in seeking payment from the Medicaid programs, the Federal Employees Health Benefit Program, and any Federal health care programs as defined in 42 U.S.C. §1320a-7b(f), for the drug Serostim; (f) misbranding the drug Serostim by promoting it for uses unapproved by the Food and Drug Administration ("FDA") and, (g) distributing human growth hormone for uses unapproved by the FDA and/or the Secretary of Health and Human Services under 21 U.S.C. § 355;
- (3) conduct by, or attributable to, Serono S.A.; Serono Holding; Ares Trading; Serono, Inc. or the Serono entities listed in Attachment A hereto, not otherwise described in this paragraph which was known to the U.S. Attorney in Massachusetts prior to the date of execution of this letter and which concerned the sale, pricing and marketing of the drug Serostim in any or all of its dose forms.

The United States does not decline criminal prosecution of Serono S.A.; Serono Holding; Ares Trading; or Serono, Inc. or any of Serono's related entities listed in Attachment A hereto, for any other conduct beyond that specifically described above, including, but not limited to, conduct involving any pharmaceutical or bio-technology product other than Serostim.

This Side Letter agreement is not intended to and does not affect the criminal liability of any individual.

It is understood among the parties to this Side Letter Agreement that the United States' promise not to prosecute Serono S.A.; Serono Holding; Ares Trading; Serono, Inc.; or the Serono entities listed in Attachment A hereto, is dependent upon and subject to Serono Labs fulfilling its obligations in the Plea Agreement and the related Civil Settlement Agreement attached hereto. If

Serono Labs does not fulfill its obligations in the Plea Agreement and the related Civil Settlement Agreement, Serono S.A.; Serono Holding; Ares Trading; Serono, Inc.; and the Serono entities listed in Attachment A hereto, agree to waive any defenses based upon the U.S. Constitution, statute of limitations, or Speedy Trial Act with respect to any and all criminal charges that could have been timely brought or pursued as of October 14, 2005.

b. Cooperation of Serono

Serono shall cooperate completely and truthfully in any trial or other proceeding arising out of any ongoing federal grand jury investigation of its current and former officers, directors, employees and agents. Serono shall make reasonable efforts to facilitate access to, and to encourage the cooperation of, its current and former officers, directors, employees and agents for interviews sought by law enforcement agents, upon request and reasonable notice. Serono shall also take reasonable measures to encourage its current and former officers, directors, employees and agents to testify truthfully and completely before any grand jury, and at any trial or other hearing, at which they are requested to do so by any government entity.

Provided, however, notwithstanding any provision of this agreement, that: (a) Serono is not required to request of its current or former officers, directors, employees and agents that they forego seeking the advice of an attorney nor that they act contrary to that advice; and (b) Serono is not required to take any action against its officers, directors, employees and agents for following their attorney's advice.

In addition, Serono shall furnish to law enforcement agents, upon request, all documents and records in its possession, custody or control relating to the conduct that is within the scope of any ongoing grand jury investigation, trial or other criminal proceeding arising out of the sales, pricing, and marketing of Serostim; and/or the purchase, sale or dissemination of Bioelectrical Impedance Analyzer ("BIA") medical devices.

Serono specifically agrees to waive any attorney-client privilege or claim of work product protection regarding conduct for which claims of an advice of counsel defense or claims of good faith defense based upon attorney advice are made by current or former officers, directors, employees and agents of Serono in the U.S. Attorney's ongoing investigation and prosecution.

c. Accounting of Costs by Serono

If applicable, for government contracting purposes and for Medicare, Railroad Retirement Medicare, TRICARE or CHAMPUS, and State Medicaid purposes, Serono agrees to treat as unallowable all costs (as defined in the Federal Acquisition Regulations ("FAR") §31.205.47(a)) incurred by or on behalf of Serono S.A.; Serono Holding; Serono Labs; and Serono, Inc. their parents, affiliates, divisions, subsidiaries, and its predecessors, successors, assigns, transferees or any of its present or former officers, directors, agents, employees, shareholders and agents in connection with (a) the matters covered by this Side Letter Agreement; (b) the Government's investigation of the matters covered by this Agreement and the corresponding civil settlement and

Corporate Integrity Agreement; (c) all investigation, defense and corrective actions resulting from the civil and criminal investigation of Serono; (d) the negotiation and performance of this agreement and the corresponding civil settlement and corporate integrity agreement; and (e) all payments made to the United States in connection therewith. If applicable, these amounts shall be separately estimated and accounted for and Serono will not charge such costs directly or indirectly to any contracts with the United States, or to any cost report submitted to the Medicare, TRICARE, State Medicaid programs or other Federal health care programs.

d. Notice to AMRO Bank N.V.

Immediately upon payment by Serono Labs or an affiliate of the Federal Settlement Amount to the United States in accordance with the Settlement Agreement, and, upon the deposit of the Medicaid State Settlement Amount into a segregated Serono account, in accordance with the Settlement Agreement, the United States shall notify ABN AMRO Bank N.V. in writing via facsimile and overnight mail that such amounts have been paid and that the letter of credit no. S863441 issued by AMRO Bank N.V. has expired.

e. Who Is Bound By Agreement

This Side Letter Agreement is binding upon the Attorney General of the United States, the United States Department of Justice, including all United States Attorneys, except that this agreement does not bind the Tax Division of the United States Department of Justice or the Internal Revenue Service of the United States Department of the Treasury.

It is expressly understood that this letter agreement will have no effect on state or local prosecuting authorities, except to the extent compromised in the settlement agreement between Serono and the State Medicaid programs.

f. Complete Agreement

This Side Letter agreement, the Plea Agreement with Serono Labs, the Civil Settlement Agreement, and the Corporate Integrity Agreement, all of which are attached hereto, are the complete and only agreement between the parties. No promises, agreements or conditions have been entered into other than those set forth or referred to in this letter. This Side Letter Agreement supersedes prior understandings, if any, of the parties, whether written or oral. This Side Letter Agreement cannot be modified other than in a written memorandum signed by the parties or on the record in court.

If this letter accurately reflects the agreement entered into between the United States and Serono S.A.; Serono Holding; Ares Trading, and Serono, Inc., and if the respective Boards of Directors of each of these entities have authorized you to enter into this Side Letter Agreement, please sign below and return the original of this letter to Assistant U.S. Attorney Mary Elizabeth Carmody.

Very truly yours,

MICHAEL J. SULLIVAN
United States Attorney
District of Massachusetts

MARY ELIZABETH CARMODY
Assistant U.S. Attorney
District of Massachusetts

ACKNOWLEDGMENT OF AGREEMENT

The Boards of Directors of each of Serono S.A.; Serono Holding; Ares Trading S.A.; and Serono, Inc. have authorized me to execute this Side Letter Agreement on behalf of each entity. Each of the Boards of Directors have read this Side Letter Agreement, the attached criminal Information charging Serono Labs, the Plea Agreement with Serono Labs, the Civil Settlement Agreement, and the Corporate Integrity Agreement in their entirety, or have been advised of the content thereof, and have discussed them fully with each entity's attorneys. Each of the Boards of Directors acknowledge that these documents fully set forth the agreements made between Serono and the United States. Each of the Boards of Directors further state that no additional promises or representations have been made to Serono by any officials of the United States in connection with the disposition of this matter, other than those set forth in this Side Letter and its attachments.

Dated:

THOMAS G. GUNNING
Vice President and General Counsel
Serono, Inc.

Dated:

THOMAS G. GUNNING
Vice President and General Counsel
Serono Holding, Inc.

Dated:

FRANCOIS NAEF
Executive Vice President and General Counsel
Serono S.A.

Dated:

FRANCOIS NAEF
Executive Vice President and General Counsel
Ares Trading S.A.

Dated:

HENRY DePIPPA, ESQUIRE
Nixon Peabody, LLP
Counsel for Serono

Dated:

MELISSA TEARNEY
Nixon Peabody, LLP
Counsel for Serono