

SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into by and between the United States of America, acting through its Department of Justice and the United States Attorney's Offices for the Districts of Massachusetts, Maryland and Connecticut, the Office of Inspector General of the United States Department of Health and Human Services ("HHS-OIG"); the United States Office of Personnel Management ("OPM"); the United States Department of Defense TRICARE Management Activity ("TMA")(collectively "the United States"); the Relators as identified in Paragraphs B through E of the Preamble to this Agreement ("Relators"); Serono, Inc., a Delaware corporation with a principal place of business in Rockland, Massachusetts; Serono Laboratories, Inc., a Massachusetts corporation with a principal place of business in Rockland, Massachusetts, (Serono, Inc., and Serono Laboratories, Inc. are hereinafter collectively referred to as "Serono"); Ares Trading S.A., a corporation duly organized under Swiss law with its registered offices in Aubonne, Switzerland, and Serono S.A., a corporation duly organized under Swiss law with its registered offices in Coisins (Vaud), Switzerland (Ares-Trading S.A. and Serono S.A. are hereinafter collectively referred to as "Serono S.A."), through their authorized representatives. Collectively, all of the above will be referred to as "the Parties."

PREAMBLE

A. WHEREAS, at all relevant times, Serono distributed, marketed and sold pharmaceutical products in the United States, including a drug they sold under the trade name Serostim;

B. WHEREAS, on or about August 17, 2000, Christine Driscoll, one of the Relators, (hereinafter the “Massachusetts Relator”), filed a qui tam action in the United States District Court for the District of Massachusetts captioned United States ex rel. Driscoll v. Serono Laboratories, Inc. et al., Civil Action No. 00-11680 (D. Mass.) (the “Driscoll Civil Action”); and, on or about May 13, 2005, Christine Driscoll and Frank Garcia, a relator identified below, filed a Third Amended Complaint in the same court under the same caption and case number and this Third Amended Complaint sets forth Driscoll’s current allegations in the qui tam action;

C. WHEREAS, on or about September 21, 2000, Sandra Boucher, William Frye, and Kimberly Jackson, three of the Relators, (hereinafter the “Maryland Relators”), filed a qui tam action in the United States District Court for the District of Maryland captioned United States ex rel. Boucher, et al. v. Serono, Inc. et al., (the “Boucher Civil Action”); and, subsequently, that action was transferred to the United States District Court for the District of Massachusetts and is currently pending in that district under Civil Action No. 05-10722 (D. Mass.);

D. WHEREAS, on or about June 26, 2002, Frank Garcia, one of the Relators, (hereinafter the “Connecticut Relator”), filed a qui tam action in the United States District Court for the District of Connecticut captioned United States ex rel. Garcia v. Serono, Inc., (the “Garcia Civil Action”); subsequently, that action was transferred to the United States District Court for the District of Massachusetts and is currently pending in that district under Civil Action No. 03-11892 (D. Mass.); and, on or about October 6, 2003, Garcia and Driscoll filed an Amended Complaint in the District of Massachusetts under the same caption and case number and this Amended Complaint sets forth Garcia’s current allegations in the qui tam action;

E. WHEREAS, in 2004, the AIDS Healthcare Foundation, Inc. (“AHF”), located in Los Angeles, California (hereinafter the “California Relator”), filed a qui tam action in the United States District Court for the Central District of California captioned United States ex rel. AIDS Healthcare Foundation v. Serono, Inc. et al., (the “ AHF Civil Action”); and, subsequently, that action was transferred to the United States District Court for the District of Massachusetts and is currently pending in that district under Civil Action No. 04-12104 (D. Mass.);

F. WHEREAS, Serono Laboratories, Inc. has agreed to enter into a plea agreement with the United States Attorney for the District of Massachusetts (the “Plea Agreement”), under which, if the Plea Agreement is approved by the Court, Serono Laboratories, Inc. will enter a plea of guilty pursuant to Fed. R. Crim. P. 11(c)(1)(C) to an Information to be filed in United States of America v. Serono Laboratories, Inc. (District of Massachusetts) (the “ Federal Criminal Action”) that will allege that (i) Serono Laboratories, Inc. violated 18 U.S.C. § 371 by conspiring to introduce and deliver for introduction into interstate commerce, with intent to defraud or mislead, adulterated medical devices; and (ii) Serono Laboratories, Inc. violated 18 U.S.C. § 371 by conspiring to knowingly and willfully pay illegal remuneration to health care providers to induce them to refer patients to pharmacies for the furnishing of the drug Serostim for which payments were made in whole or in part by the Medicaid Program;

G. WHEREAS, Serono and Serono S.A. have entered into or will be entering into separate settlement agreements (hereinafter referred to as the "Medicaid State Settlement Agreements") with the states which will be receiving settlement funds from Serono or Serono

S.A. pursuant to Paragraph 1(B) below for the Covered Conduct described in Paragraph I below (hereinafter referred to as the “Medicaid Participating States”);

H. WHEREAS, the United States and the Medicaid Participating States allege that Serono caused to be submitted claims for payment for Serostim to their Medicaid Programs, established pursuant to or in connection with Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v (the “Medicaid Program”); and the United States further alleges that Serono caused to be submitted claims for payment of Serostim to the TRICARE Program (formerly known as the Civilian Health and Medical Program of the Uniformed Services (“CHAMPUS”)), 10 U.S.C. §§ 1071-1110, which is administered by the Department of Defense through TMA, and to the Federal Employees Health Benefits Program ("FEHBP") and that Serono caused purchases of Serostim by the Department of Veterans Affairs (“DVA”);

I. WHEREAS, the United States contends that it has claims under the False Claims Act, 31 U.S.C. §§ 3729-3733, and that it and the Medicaid Participating States (hereinafter collectively referred to as the "Government") have certain other civil claims against Serono for allegedly engaging in the following conduct with respect to the marketing, promotion and sale of Serostim (hereinafter referred to as the "Covered Conduct"):

(i) The Government alleges that, from as early as September 1996, Serono conspired with others, in violation of 18 U.S.C. § 371, to introduce and deliver for introduction into interstate commerce, with intent to defraud or mislead, adulterated medical devices in the form of computer software devices for use in conjunction with bioelectrical impedance analysis (“BIA”) devices, to be used as a tool for calculating body cell mass and/or diagnosing AIDS

wasting. The Government further alleges that the software devices were adulterated because Serono and others had not obtained premarket approval from the United States Food and Drug Administration (“FDA”) to introduce these devices into interstate commerce for these uses. Furthermore, the Government contends that, during the time period 1998 to 2004, Serono knowingly caused false and/or fraudulent claims to be submitted to the Medicaid, FEHBP, and TRICARE Programs for Serostim and knowingly caused the DVA to purchase Serostim which had been dispensed to patients based on testing using this adulterated medical device;

(ii) The Government contends that, during the period of 1998 to 2004, Serono knowingly and willfully promoted the sale and use of Serostim for lipodystrophy (i.e. a separate condition involving weight gain in the midsection and/or weight loss in the extremities) and body cell mass (“BCM”) wasting (i.e., AIDS wasting defined as a purported loss of or deficient body cell mass), uses for which the FDA has not approved Serostim, i.e., Serono promoted Serostim for "unapproved" or "off-label" uses. The Government further contends that Serono's promotion of Serostim for these unapproved uses violated the Food Drug and Cosmetic Act, 21 U.S.C. §§ 331(a) & (d). Furthermore, the Government contends that, the uses of Serostim for lipodystrophy and BCM wasting are also not medically accepted indications for which State Medicaid Programs may reimburse and that, during this time period, Serono knowingly caused false and/or fraudulent claims to be submitted to the Medicaid, FEHBP, and TRICARE Programs for Serostim and caused the DVA to purchase Serostim which had been dispensed to patients for these indications;

(iii) The Government contends that, as part of Serono’s marketing and sale of

Serostim from 1997 to 2001, Serono knowingly and willfully offered and paid illegal remuneration (including, but not limited to, providing free BIA devices and software, free trips to Cannes, France and SeronAIDS and SALSA survey payments) to physicians in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2). Furthermore, the Government contends that, during this time period, Serono knowingly caused the submission of false and/or fraudulent claims to the Medicaid and TRICARE Programs for Serostim and caused the DVA to purchase Serostim by inducing physicians to prescribe Serostim to patients by providing free BIA devices and software, free trips to Cannes, France and SeronAIDS and SALSA payments to them; and

(iv) The Government contends, that during the period 1997 to 2000, Serono knowingly and willfully offered and paid illegal remuneration in the form of rebates and discounts to specialty pharmacies in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2). Furthermore, the Government contends that, during this time period, Serono knowingly caused the submission of false and/or fraudulent claims to the Medicaid Program by inducing these pharmacies to recommend Serostim or arrange for the use of Serostim by providing the rebates and discounts to them;

J. WHEREAS, this Agreement is neither an admission of facts nor liability by Serono (with the exception of such admissions as Serono Laboratories, Inc. makes in connection with any guilty plea to the Information referenced in Paragraph F above and accepted by the Court) nor a concession by the Government that its claims are not well founded;

K. WHEREAS, HHS-OIG contends that it has certain administrative claims, as specified in Paragraph 4 below, against Serono for engaging in the Covered Conduct;

L. WHEREAS, the United States and the Relators have reached an agreement with respect to the Relators' claim of entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement;

M. WHEREAS, the Relators and Serono have reached an agreement with respect to the Relators' claim of entitlement under 31 U.S.C. § 3730(d) to attorney's fees and costs; and

N. WHEREAS, to avoid the delay, expense, inconvenience and uncertainty of protracted litigation of these claims, the Parties mutually desire to reach a full and final settlement as set forth below:

TERMS AND CONDITIONS

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants, and obligations in this Agreement, and for good and valuable consideration, receipt of which is hereby acknowledged, the Parties agree as follows:

1. Serono S.A. and Serono shall pay to the United States and the Medicaid Participating States, collectively, the sum of \$567,065,000, plus interest at the average trust fund rate of 4.375% per annum (\$67,970.12 per day) on \$567,065,000 from June 8, 2005 and continuing until and including the day before complete payment is made (the "Settlement Amount"). This sum shall constitute a debt immediately due and owing to the United States on the satisfaction of the conditions of payment set forth in Subparagraph A of this Paragraph and to the Medicaid Participating States on the satisfaction of the conditions of payment set forth in Subparagraph B of this Paragraph. This debt is to be discharged by payments to the United

States and the Medicaid Participating States under the following terms and conditions:

A. Serono S.A. and Serono shall pay to the United States the sum of \$305,077,000, plus interest accrued thereon at the rate of 4.375% per annum (\$36,567.45 per day) from June 8, 2005 continuing until and including the day before complete payment is made (the "Federal Settlement Amount"). The Federal Settlement Amount shall be paid by electronic funds transfer no later than seven (7) business days after Serono and Serono S.A. receive written payment instructions from the United States and following the latest of the dates on which the following occurs: (1) this Agreement is fully executed by the Parties and delivered to Serono's attorneys; or (2) the Court accepts a Fed. R. Crim. P. 11(c)(1)(C) guilty plea from Serono Laboratories, Inc. as described in Preamble F in connection with the Federal Criminal Action and imposes the agreed upon sentence. (The date of payment by Serono and Serono, S.A. to the United States is the "Payment Date.")

B. Serono S.A. and Serono shall pay to the Medicaid Participating States the sum of \$261,988,000, plus interest accrued thereon at a rate of 4.375% per annum (\$31,402.67 per day) from June 8, 2005 continuing until and including the day before complete payment is made into an interest-bearing account (the "Medicaid State Settlement Amount"), under the terms and conditions of the Medicaid State Settlement Agreements. This Medicaid State Settlement Amount shall be paid pursuant to the Medicaid State Settlement Agreements no later than seven (7) business days following the latest date on which the following occurs: (1) this Agreement is fully executed by the Parties and delivered to Serono's attorneys; and (2) the Court accepts a Fed. R. Crim. P. 11(c)(1)(C) guilty plea in connection with the Federal Criminal

Action as described in Preamble Paragraph F and imposes the agreed upon sentence. The Medicaid State Settlement Amount shall be paid to the Medicaid Participating States from such account following execution of the State Settlement Agreements with all the Medicaid Participating States, or at any earlier date as otherwise agreed in writing between Serono and the National Association of Medicaid Fraud Control Units Settlement Team.

C. Contingent upon the United States receiving the Federal Settlement Amount from Serono and Serono S.A. and as soon as feasible after such receipt, the United States agrees to pay (1) to the Massachusetts Relator the amount of \$16,940,000 plus the actual accrued interest paid to the United States by Serono and Serono S.A. on that principal amount from June 8, 2005, through the Payment Date , and (2) to the Maryland Relators the amount of \$34,923,000 plus the actual accrued interest paid to the United States by Serono and Serono S.A. on that principal amount from June 8, 2005, through the Payment Date. Both such payments will be made by electronic funds transfers. It is expressly understood and agreed that the United States in no way promises, guarantees, nor is liable to Relators for the collection or payment of any funds pursuant to this Agreement or the payment of the Relators' share except as provided herein for funds actually collected and received by the United States.

D. Serono S.A. and Serono shall pay attorneys' fees to the Massachusetts, Maryland and Connecticut Relators in the amount of \$595,000. This amount shall be paid as an electronic funds transfer to these Relators' attorneys (to be allocated in accordance with their instructions) no later than seven (7) business days after the stipulations of dismissal are filed as set forth in Paragraph 10.

E. If Serono Laboratories, Inc.'s agreed upon guilty plea pursuant to Fed. R. Crim. P. 11(c)(1)(C) in the Federal Criminal Action described in Preamble Paragraph F is not accepted by the Court or the Court does not impose the agreed upon disposition for whatever reason, this Agreement shall be null and void at the option of either the United States or Serono or Serono S.A.. If either the United States or Serono or Serono S.A. exercises this option, which option shall be exercised by notifying all Parties, through counsel, in writing within ten (10) business days of the Court's decision, the Parties will not object and this Agreement will be rescinded. If this Agreement is rescinded, Serono will not plead, argue or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel or similar theories, to any such civil or administrative claims, actions or proceedings which are brought by the United States within 90 calendar days of notification to all other Parties of that rescission, except to the extent such defenses were available before July 1, 2003.

2. Subject to the exceptions in Paragraphs 3, 4, 5 and 6 below, in consideration of the obligations of Serono S.A. and Serono set forth in this Agreement, conditioned upon Serono S.A. and Serono's payment in full of the Settlement Amount, subject to Paragraph 18 below (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement, as defined below), and subject to the acceptance by the United States District Court for the District of Massachusetts of a guilty plea by Serono Laboratories, Inc. described in Preamble Paragraph F and the imposition of the agreed upon sentence, the United States, on behalf of itself, and its officers, agents, agencies, and departments, as set forth above, hereby fully and finally releases Serono S.A. and Serono, their predecessors, subsidiaries, corporate

parents and affiliates, successors and assigns, and their current and former directors, officers and employees from any civil or administrative monetary claim that the United States has or may have under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; any statutory provision applicable to the federally-funded programs in this Agreement for which the Civil Division, United States Department of Justice, has actual and present authority to assert and compromise pursuant to 28 C.F.R. Part 0, Subpart I, § 0.45(d); and common law claims for fraud, payment by mistake, unjust enrichment or disgorgement for the Covered Conduct.

3. Notwithstanding any term of this Agreement, the United States specifically does not herein release any person or entity from any of the following claims or liabilities: (a) any potential criminal, civil or administrative claims arising under Title 26, U.S. Code (Internal Revenue Code); (b) any criminal liability; (c) any potential liability to the United States (or any agencies thereof) for any conduct other than the Covered Conduct; (d) any claims based upon obligations created by this Agreement; (e) except as explicitly stated in Paragraphs 2, 4, 5, and 6 of this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs; (f) any express or implied warranty claims or other claims for defective or deficient products and services; (g) any claims for personal injury or property damage or for other consequential damages arising from the Covered Conduct; (h) any claim based on a failure to deliver items or services due; or (i) any civil or administrative claims against individuals, including current and former directors, officers, and employees of Serono, its predecessors, subsidiaries, and its corporate parent and affiliates, who, related to the Covered Conduct, receive

written notification that they are the target of a criminal investigation, are criminally indicted or charged, or are convicted, or who enter into a criminal plea agreement.

4. In consideration of the obligations of Serono S.A. and Serono set forth in this Agreement and of Serono Holding, Inc. (the US parent of Serono, Inc.) in the Corporate Integrity Agreement (“CIA”) incorporated herein by reference, conditioned upon Serono S.A. and Serono’s payment in full of the Settlement Amount, and subject to Paragraph 18 below (concerning bankruptcy proceedings commenced within 91 days of the effective date of this Agreement), the HHS-OIG agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid or other Federal healthcare programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Serono S.A., Serono Inc., and except for Serono Laboratories, Inc., their predecessors, subsidiaries, and corporate parents, affiliates, successors, and assigns under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law), or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities), for the Covered Conduct except as reserved in Paragraph 3 above, and as reserved in this Paragraph. The HHS-OIG expressly reserves all rights to comply with any statutory obligations to exclude Serono S.A., Serono, or their predecessors, subsidiaries, and corporate parents, affiliates, successors, and assigns from the Medicare, Medicaid, or other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the HHS-OIG from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 3 above.

5. In consideration of the obligations of Serono S.A. and Serono set forth in this Agreement, conditioned upon Serono S.A. and Serono's full payment of the Settlement Amount, and subject to Paragraph 18 below (concerning bankruptcy proceedings commenced within 91 days of the effective date of this Agreement or any payment under this Agreement), TMA agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion or suspension from the TRICARE Program against Serono S.A. or Serono and their predecessors, subsidiaries, corporate parents, affiliates, successors and assigns, or their current directors, officers or employees under 32 C.F.R. § 199.9 for the Covered Conduct, except as reserved in Paragraph 3 above, and as reserved in this Paragraph. TMA expressly reserves its authority under 32 C.F.R. § 199.9 (f)(1)(i)(A), (f)(1)(i)(B), and (f)(1)(iii), based upon the Covered Conduct. Nothing in this Paragraph precludes TMA or the TRICARE Program from taking action against entities or persons, or for conduct and practices, for which civil claims have been reserved in Paragraph 3 above.

6. In consideration of the obligations of Serono S.A. and Serono in this Agreement, conditioned upon Serono S.A. and Serono's full payment of the Settlement Amount, and subject to Paragraph 18 below (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement or any payment under this Agreement), OPM agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking debarment from FEHBP against Serono S.A. or Serono and their predecessors, subsidiaries, corporate parents, affiliates, successors and assigns, or their current directors, officers or employees under 5 U.S.C. § 8902a or 5 C.F.R. Part 890 for the Covered Conduct, except as

reserved in Paragraph 3 above and except if excluded by the OIG-HHS pursuant to 42 U.S.C. § 1320a-7(a). Nothing in this Paragraph precludes OPM from taking action against entities or persons, or for conduct and practices, for which civil claims have been reserved in Paragraph 3 above.

7. The Parties each represent that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

8. Relators agree that settlement of the Civil Actions for the Federal Settlement Amount and the allocation of the amounts to the various claims is fair, adequate and reasonable under all the circumstances and that they will not challenge the settlement or this Agreement pursuant to 31 U.S.C. § 3730(c)(2)(B), and they expressly waive the opportunity for a hearing on any objection to this Agreement pursuant to 31 U.S.C. § 3730(c)(2)(B).

Furthermore, conditioned upon receipt by the Massachusetts and Maryland Relators of the Relators' share as set forth in Paragraph 1(C), all Relators, for themselves individually, and for their heirs, successors, agents and assigns, fully and finally release, waive, and forever discharge the United States, its agencies (including, but not limited to, TMA, OPM, HHS-OIG and DVA), employees, servants, and agents from any claims arising from or relating to 31 U.S.C. § 3730, including 31 U.S.C. §§ 3730(b), (c), (c)(5), (d), and (d)(1), from any claims arising from the filing of the Civil Action, and from any other claims for a share of the Settlement Amount, and in full settlement of any claims Relators may have under this Agreement. This Agreement does not resolve or in any manner affect any claims the United States has or may have against the Relators arising under Title 26, U.S. Code (Internal Revenue Code), or any claims arising under

this Agreement. This Agreement does not resolve or in any manner affect the pendant claims based on State *qui tam* statutes set forth in the civil actions identified in Paragraphs B and D of the Preamble to this Agreement.

9. In consideration of the obligations of the United States set forth in this Agreement, Serono S.A. and Serono and their predecessors, subsidiaries, corporate parents and affiliates fully and finally release the United States, its agencies (including, but not limited to, TMA, OPM, HHS-OIG and DVA), employees, servants, and agents from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) which they have asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to or arising from the United States' investigation and prosecution of the civil actions identified in Paragraphs B through E of the Preamble to this Agreement, the Federal Criminal Action, and the Covered Conduct.

10. Upon execution of this Agreement by all parties, the United States will file notices of intervention in the civil actions identified in Paragraphs B through E of the Preamble to this Agreement as to those claims relating to the Covered Conduct. Within seven (7) business days after the payment of the Federal Settlement Amount pursuant to this Agreement, the United States and Relators will file stipulations of dismissal as to the Serono and Serono S.A. defendants named in the civil actions identified in Paragraphs B through E of the Preamble to this Agreement in the form of the stipulations of dismissal attached hereto as Attachments A, B, C, and D. The federal claims in the civil actions identified in Paragraphs B through E of the Preamble shall be dismissed against the Serono S.A. and Serono defendants named in the civil

actions identified in Paragraphs B through E of the Preamble to this Agreement effective upon receipt by the United States of the Federal Settlement Amount to the extent set forth in the stipulations of dismissal attached hereto.

11. In consideration of the obligations of Serono S.A. and Serono set forth in this Agreement, the Relators, for themselves, and for their heirs, successors, attorneys, agents, and assigns, hereby fully and finally release Serono S.A. and Serono and their predecessors, subsidiaries, corporate parents and affiliates, successors and assigns and their current and former directors, officers, employees and attorneys from any claims or allegations which the Relators have asserted, could have asserted or may assert in the future against any of them, whether or not related to or arising from the United States' investigation and prosecution of the qui tam actions, the Federal Criminal Action and the Covered Conduct, including without limitation, claims relating to or arising under the False Claims Act, 31 U.S.C. §§ 3729-3733, and common law; provided, however, that nothing in this Agreement resolves or in any manner affects the pendant claims based on State *qui tam* statutes set forth in the civil actions identified in Paragraphs B and D of the Preamble to this Agreement.

12. In consideration of the obligations of the Relators set forth in this Agreement, Serono S.A. and Serono, and their predecessors, subsidiaries, corporate parents and affiliates, and all of their agents, successors and assigns, hereby fully and finally release the Relators and their respective heirs, successors, assigns, agents and attorneys from any claims they have asserted, could have asserted, or may assert in the future against any of the relators whether or not relating to the qui tam actions.

13. Serono S.A. and Serono waive and will not assert any defenses they may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. Nothing in this Paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

14. The Settlement Amount that must be paid pursuant to Paragraph 1 above will not be decreased as a result of the denial of claims for payment now being withheld from payment by any State or Federal payer, related to the Covered Conduct; and, if applicable, Serono S.A. and Serono agree not to resubmit or cause anyone to resubmit to any State or Federal payer any previously denied claims, which denials were based on the Covered Conduct and agree not to appeal or cause the appeal of any such denials of claims.

15. Serono S.A. and Serono agree to the following:

A. Unallowable Costs Defined: that all costs (as defined in the Federal Acquisition Regulations (FAR) 48 C.F.R. § 31.205-47 and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395ggg and 1396-1396v, and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Serono S.A. or Serono, their predecessors, subsidiaries, corporate parents and affiliates, successors and assigns and their present or former officers, directors, employees, shareholders, and agents in connection with: (1)

the matters covered by this Agreement and the related Plea Agreement; (2) the United States' civil and criminal investigation of the matters covered by this Agreement; (3) Serono S.A. and Serono's investigation, defense, and any corrective actions undertaken in direct response to the United States' civil and criminal investigations in connection with the matters covered by this Agreement (including attorneys' fees); (4) the negotiation and performance of this Agreement, the Plea Agreement, and the Medicaid State Settlement Agreements; (5) the payments made to the United States or any State pursuant to this Agreement, the Plea Agreement, or the Medicaid State Settlement Agreements and any payments that Serono S.A. and Serono may make to Relators; (6) the negotiation of, and the obligations undertaken pursuant to the CIA, including to (i) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and (ii) prepare and submit reports to the HHS-OIG, are unallowable costs on Government contracts with DVA and other agencies and under the Medicare Program, Medicaid Program, TRICARE Program, and FEHBP. However, nothing in this Paragraph affects the status of costs that are not allowable based on any other authority applicable to Serono S.A. and Serono. (All costs described or set forth in this Paragraph 15(A) are hereafter, "unallowable costs").

B. Future Treatment of Unallowable Costs: If applicable, these unallowable costs will be separately estimated and accounted for by Serono S.A. and Serono, and they will not charge such unallowable costs directly or indirectly to any contracts with the United States or any State Medicaid Program, or seek payment for such unallowable costs through any cost report, cost statement, information statement, or payment request submitted by them or any of

their subsidiaries to Medicare, Medicaid, TRICARE, FEHBP or DVA.

C. Treatment of Unallowable Costs Previously Submitted for Payment: If applicable, Serono S.A. and Serono further agree that within 60 days of the effective date of this Agreement, they will identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid, DVA and FEHBP fiscal agents, any unallowable costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid Program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Serono S.A. or Serono or any of their subsidiaries, and will request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. Serono S.A. and Serono agree that the United States, at a minimum, will be entitled to recoup from Serono S.A. or Serono any overpayment plus applicable interest as a result of the inclusion of such unallowable costs on previously-submitted cost reports, information reports, cost statements, or requests for payment. Any payment due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice, and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Serono S.A., Serono or any of their subsidiaries on the effect of inclusion of unallowable costs (as defined in this Paragraph) on Serono S.A.'s, Serono's or any of their subsidiaries' cost reports, cost statements, or information reports. Nothing in this Agreement shall constitute a waiver of the rights of the United States to examine or reexamine the unallowable costs described in this Paragraph.

16. If applicable, Serono S.A. and Serono agree that they will not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents or sponsors. Serono S.A. and Serono waive any causes of action against these beneficiaries or their parents or sponsors based upon the claims for payment covered by this Agreement.

17. Serono S.A. and Serono expressly warrant that they have reviewed their financial situations and that they are currently solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and will remain solvent following payment to the United States hereunder. Further, the Parties expressly warrant that, in evaluating whether to execute this Agreement, the Parties (a) have intended that the mutual promises, covenants and obligations set forth herein constitute a contemporaneous exchange for new value given to Serono S.A. and Serono, within the meaning of 11 U.S.C. § 547(c)(1), and (b) have concluded that these mutual promises, covenants and obligations do, in fact, constitute such a contemporaneous exchange.

18. In the event Serono S.A. or Serono commences, or another party commences, within 91 days of the Effective Date of this Agreement (defined below), any case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization or relief of debtors, (a) seeking to have any order for relief of Serono S.A.'s or Serono's debts, or seeking to adjudicate Serono S.A. or Serono as bankrupt or insolvent, or (b) seeking appointment of a receiver, trustee, custodian or other similar official for Serono S.A. or Serono or for all or any substantial part of their assets, Serono S.A. and Serono respectively agree that:

A. Serono S.A.'s and Serono's obligations under this Agreement may not be

avoided pursuant to 11 U.S.C. § 547 or 548, and Serono S.A. and Serono will not argue or otherwise take the position in any such case, proceeding or action that: (i) Serono S.A.'s or Serono's obligations under this Agreement may be avoided under 11 U.S.C. § 547 or 548; (ii) Serono S.A. or Serono was insolvent at the time this Agreement was entered into, or became insolvent as a result of the payment made to the United States hereunder; or (iii) the mutual promises, covenants and obligations set forth in this Agreement do not constitute a contemporaneous exchange for new value given to Serono S.A. and Serono;

B. In the event that Serono S.A.'s and Serono's obligations hereunder are avoided for any reason, including, but not limited to, the exercise of a trustee's avoidance powers under the Bankruptcy Code, the United States, at its sole option, may rescind the releases in this Agreement, and bring any civil and/or administrative claim, action or proceeding against Serono S.A. and Serono for the claims that would otherwise be covered by the releases provided in this Agreement. If the United States chooses to do so, Serono S.A. and Serono agree that, for purposes only of any case, action, or proceeding referenced in the first clause of this Paragraph, (i) any such claims, actions or proceedings brought by the United States (including any proceedings to exclude Serono Laboratories, Inc. from participation in Medicare, Medicaid, or other federal health care programs) are not subject to an "automatic stay" pursuant to 11 U.S.C. Section 362(a) as a result of the action, case or proceeding described in the first clause of this Paragraph, and that Serono S.A. and Serono will not argue or otherwise contend that the United States' claims, actions or proceedings are subject to an automatic stay; (ii) that Serono S.A. and Serono will not plead, argue or otherwise raise any defenses under the theories of statute of

limitations, laches, estoppel or similar theories, to any such civil or administrative claims, actions or proceedings which are brought by the United States within 30 calendar days of written notification to Serono that the releases herein have been rescinded pursuant to this Paragraph, except to the extent such defenses were available before July 1, 2003; and (iii) the United States and the Participating States have valid claims against Serono S.A. and Serono in the aggregate amount of at least \$567,065,000, and they may pursue their claims, inter alia, in the case, action or proceeding referenced in the first clause of this Paragraph, as well as in any other case, action, or proceeding; and

C. Serono S.A. and Serono acknowledge that their agreements in this Paragraph are provided in exchange for valuable consideration provided in this Agreement.

19. Except as otherwise stated in this Agreement, this Agreement is intended to be for the benefit of the Parties only, and by this instrument the Parties do not release any claims against any other person or entity.

20. Nothing in any provision of this Agreement constitutes an agreement by the United States, Serono S.A., Serono or the Relators concerning the characterization of the Settlement Amount or the relators' share for purposes of the Internal Revenue Laws, Title 26 of the United States Code.

21. Each party to this Agreement will bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement, except as specified in Paragraph 1(D) above.

22. Serono Holding, Inc. has entered into a CIA with HHS-OIG, attached as

Attachment E, which is incorporated into this Agreement by reference. Serono Holding, Inc. and its United States subsidiaries and affiliates will immediately upon execution of this Agreement begin to implement their obligations under the CIA.

23. Serono shall cooperate completely and truthfully in any trial or other proceeding arising out of any ongoing federal 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 and testimony sought by the United States, 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 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: (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 the United States, upon request, all documents and records in its possession, custody or control relating to the conduct that is within the scope of any ongoing federal investigation, trial or other 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 any federal investigation, trial or other proceeding.

24. This Agreement is governed by the laws of the United States. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties under this Agreement will be the United States District Court for the District of Massachusetts, except that disputes arising under the CIA incorporated herein by reference shall be resolved through the dispute resolution provisions set forth in the CIA.

25. The undersigned Serono S.A. and Serono signatories represent and warrant that they are authorized by their Board of Directors to execute this Agreement. The undersigned signatory or signatories for each Relator represent and warrant that they are authorized to execute this Agreement on behalf of that Relator. The undersigned United States signatories represent that they are signing this Agreement in their official capacities and they are authorized to execute this Agreement on behalf of the United States through their respective agencies and departments, and, in the case of the HHS-OIG and TMA, on behalf of their respective departments.

26. This Agreement is effective on the date of signature of the last signatory to the Agreement (the "Effective Date"). Facsimiles of signatures shall constitute acceptable binding signatures for purposes of this Agreement.

27. This Agreement shall be binding on all successors, transferees, heirs and assigns of the Parties.

28. This Agreement and Attachments A through D attached hereto, together with the CIA, which is Attachment E, incorporated by reference, and the Plea Agreement described in Preamble Paragraph F, and the Side Letter Agreement entered into between counsel for Serono S.A., Serono Holding, Inc., Ares-Trading S.A. and Serono, Inc. and the Criminal Division of the U.S. Attorney's Office for the District of Massachusetts, constitute the complete agreement between the Parties with regard to the Covered Conduct. This Agreement may not be amended except by written consent of all the Parties, except that only Serono Holding, Inc. and HHS-OIG must agree in writing to a modification of the CIA, without the consent of any other party to this Agreement or the Plea Agreement.

29. The Relators, Serono S.A. and Serono hereby consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

30. This Agreement may be executed in counterparts, each of which shall constitute an original and all of which shall constitute one and the same Agreement.

UNITED STATES OF AMERICA

MICHAEL J. SULLIVAN
U.S. Attorney, District of Massachusetts

By: _____

JENNIFER C. BOAL
Civil Chief
PATRICIA CONNOLLY
Assistant U.S. Attorney
United States Attorney's Office
District of Massachusetts

Dated:

PETER D. KEISLER
Assistant Attorney General

By: _____

MICHAEL F. HERTZ
Director
JOYCE R. BRANDA
Deputy Director
CAROL LYNN WALLACK
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

Dated:

ROD J. ROSENSTEIN
United States Attorney

By: _____

ROANN NICHOLS
Assistant United States Attorney
United States Attorney's Office
District of Maryland

Dated:

KEVIN J. O'CONNOR
United State Attorney

By: _____
RICHARD M. MOLOT
Assistant United States Attorney
United States Attorney's Office
District of Connecticut

Dated:

By: _____
LEWIS MORRIS
Chief Counsel to the Inspector General
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services

Dated:

By: _____
LAUREL C. GILLESPIE
Deputy General Counsel
TRICARE Management Activity
United States Department of Defense

Dated:

By: _____
FRANK D. TITUS
Assistant Director for
Insurance Services Programs
United States Office of Personnel Management

Dated:

By: _____
E. JEREMY HUTTON
Assistant Inspector General for Legal Affairs
United States Office of Personnel Management

Dated:

SERONO, INC. AND SERONO LABORATORIES, INC.

By: _____
THOMAS G. GUNNING
Vice President and General Counsel
Serono, Inc. and Serono Laboratories, Inc.

Dated:

By: _____
HENRY DEIPPO
MELISSA TEARNEY
Nixon, Peabody LLP

Dated:

SERONO S.A. AND ARES TRADING S.A.

By: _____
FRANCOIS NAEF
Executive Vice President and General Counsel

Dated:

By: _____
HENRY DEIPPO
MELISSA TEARNEY
Nixon, Peabody LLP

Dated:

RELATORS

By: _____
Christine Driscoll

Dated:

By: _____
Carl Valvo
Cosgrove Eisenberg & Kiley PC
Counsel to Relator Driscoll

Dated:

By: _____
Sandra Boucher

Dated:

By: _____
William Frye

Dated:

By: _____
Kimberly Jackson

Dated:

By: _____
J. Stephen Simms, Esq.
W. Charles Bailey, Jr., Esq.
Simms Shower LLP
Counsel to Relators Boucher, Frye, and Jackson

Dated:

By: _____
Frank Garcia

Dated:

By: _____
Robert M. Thomas, Jr.
Thomas & Associates
Counsel to Relator Garcia

Dated:

By: _____
Tom Myers on behalf of AHF

Dated:

By: _____
Lawrence M. Kraus
Foley & Lardner
Counsel for Relator AHF

Dated:

