



**U.S. Department of Justice**

***Michael J. Sullivan***  
*United States Attorney*  
*District of Massachusetts*

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*Main Reception: (617) 748-3100*

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

October 12, 2005

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

Attorney Melissa Tearney  
Nixon Peabody, LLP  
100 Summer Street  
Boston, MA 02110

**Re: United States v. Serono Laboratories, Inc.**

Dear Mr. DePippo and Ms. Tearney:

This letter sets forth the Agreement between the United States Department of Justice and the United States Attorney for the District of Massachusetts (the "U.S. Attorney") (collectively, the United States Department of Justice and the U.S. Attorney will be referred to as the "United States"), and your client, Serono Laboratories, Inc. (a Massachusetts Corporation) ("Serono Labs"), a subsidiary of Serono Holding, Inc. (collectively referred to as "the Parties"), as follows:

1. Change of Plea

On or before October 21, 2005, or such other date as the Court may set, Serono Labs shall waive indictment and plead guilty to the two-count Information attached hereto as Exhibit A. Count One of the Information charges that, from as early as September 1996, through at least January 2002, Serono Labs 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. Count Two of the Information charges that, from on or about March 1, 1999, through in or about December 1999, Serono Labs 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. Serono Labs expressly and unequivocally admits that it knowingly, intentionally and willfully committed the crimes charged in the attached Information

and is in fact guilty of these offenses. Defendant Serono Labs agrees to waive venue, to waive any applicable statutes of limitations, and to waive any defects in the Information.

2. Penalties

With respect to each count, the Defendant Serono Labs is subject to a fine of \$500,000, or twice the gross gain derived from the offense or twice the gross loss to a person other than the defendant, whichever is greatest. *See* 18 U.S.C. §§ 3571(c), (d). With respect to Count One, the gross loss resulting from the offense is \$104,914,000, and the maximum fine with respect to Count One is therefore \$209,828,000. With respect to Count Two, the gross loss resulting from the offense is \$9,200,000 and the maximum fine with respect to Count Two is therefore \$18,400,000.

With respect to each count, the Defendant Serono Labs may be sentenced to a term of probation of up to five (5) years. *See* 18 U.S.C. § 3561(c)(1).

With respect to each count, the Defendant Serono Labs shall pay a special assessment of \$400.00. *See* 18 U.S.C. § 3013(a)(2)(B).

Additionally, the Court may order restitution to any victims of the offenses.

3. Sentencing Guidelines

The sentence to be imposed upon Defendant is within the discretion of the sentencing Court, subject to the statutory maximum penalties set forth above, and the provisions of the Sentencing Reform Act and the United States Sentencing Guidelines promulgated thereunder, as modified by *United States v. Booker* and *United States v. Fanfan*, 125 S.Ct. 738, 2005 WL 50108 (January 12, 2005). In imposing the sentence, the Court must consult and take into account the United States Sentencing Guidelines, along with the other factors set forth in 18 U.S.C. § 3553(a).

The parties agree that the following provisions of the United States Sentencing Guidelines (“U.S.S.G.”) apply to the sentencing of Serono Labs with respect to the Information:

- a. The Guideline Manual in effect as of November 1, 2001, should be used in determining the defendant's sentence with respect to Counts One and Two. *See* U.S.S.G. § 1B1.11(b)(3) (Nov. 1, 2001).
- b. Calculating the Base Fine - \$114,113,000
  - i. Per U.S.S.G. § 8C2.4(a) (Nov. 1, 2001), the base fine is the greatest of the amount of fine determined by reference to U.S.S.G. § 8C2.4(d) corresponding to the calculated offense level, the gross pecuniary gain to the organization from the offense, or the pecuniary loss from the offense caused by the organization.

- (1) Calculated offense level is 38 with a corresponding offense level fine table amount of \$72,500,000, as determined as follows:
- (a) The two offenses group pursuant to U.S.S.G. § 3D1.2(d), and the total aggregate harm is \$114,113,000 determined as follows: the minimum fraud loss resulting from the conduct alleged in Count One (conspiracy to introduce and deliver for introduction into interstate commerce, with intent to defraud or mislead, adulterated devices) is \$104,914,000, and the losses resulting from Count Two (conspiracy to offer and pay illegal remunerations to health care providers) is \$9,200,000.
  - (b) The Guideline applicable to Count One (conspiracy to deliver for introduction into interstate commerce, with intent to defraud or mislead, adulterated devices) is U.S.S.G. § 2B1.1 (Nov. 1, 2001). *See* U.S.S.G. §§ 2X1.1 (Nov. 1, 2001), 2N2.1(b)(1) (Nov. 1, 2001).
  - (c) The Guideline applicable to Count Two (conspiracy to pay illegal remunerations to health care providers) is U.S.S.G. § 2B4.1 (Nov. 1, 2001). *See* U.S.S.G. § 2X1.1 (Nov. 1, 2001).
  - (d) Per the grouping rule found at U.S.S.G. § 3D1.3(b) and Application Note 3 (Nov. 1, 2001), when counts in the group are covered by different guidelines, the guideline that produces the highest offense level using the aggregate behavior is to be used. In this case, that is the fraud guideline:

Fraud Guideline (U.S.S.G. § 2B1.1 (Nov. 1, 2001)):

- (i) The base offense level under the fraud guideline is six (6) pursuant to U.S.S.G. § 2B1.1 (Nov. 1, 2001).
- (ii) The pecuniary loss intended by Serono Labs from the offense is in excess of \$100,000,000, thereby adding 26 levels pursuant to U.S.S.G. § 2B1.1(b)(1)(N) (Nov. 1, 2001).
- (iii) There were more than 50 victims of the offense, thereby adding four (4) levels pursuant to U.S.S.G. 2B1.1(b)(2)(B) (Nov. 1, 2001).

- (iv) The offense involved use of sophisticated means, thereby adding two (2) levels pursuant to U.S.S.G. § 2B1.1(b)(8) (Nov. 1, 2001).
- (v) The total offense level is 38.

Commercial Bribery Guideline (U.S.S.G. § 2B4.1 (Nov. 1, 2001))

(vi) The base offense level under the commercial bribery guideline is eight (8) pursuant to U.S.S.G. § 2B4.1(a) (Nov. 1, 2001).

(vii) The pecuniary loss intended by Serono Labs from the offense is in excess of \$100,000,000, thereby adding 26 levels pursuant to U.S.S.G. §§ 2B4.1(b)(1) (Nov. 1, 2001), 2B1.1(b)(1)(N) (Nov. 1, 2001).

(viii) The total offense level is 34.

(e) A total base offense level of 38 has a corresponding fine of \$72,500,000 pursuant to U.S.S.G. § 8C2.4(d) (Nov. 1, 2001).

(2) Pursuant to U.S.S.G. § 8C2.4(a)(2) (Nov. 1, 2001), the pecuniary gain to the organization from the offenses was \$90,068,000.

(3) Pursuant to U.S.S.G. § 8C2.4(a)(3) (Nov. 1, 2001), the pecuniary losses from the offenses caused by the organization was \$114,113,000. *See also* U.S.S.G. § 2B4.1(c)(1) (Nov. 1, 2001) (defining how to determine pecuniary losses in offenses involving organizations).

ii. The base fine is therefore \$114,113,000 pursuant to U.S.S.G. § 8C2.4(a) (Nov. 1, 2001).

c. Calculating the Multiplier: 1.2 - 2.4

i. Pursuant to U.S.S.G. § 8C2.5 (Nov. 1, 2001), the culpability score is 6 as determined as follows:

(1) Base culpability score is five (5) pursuant to U.S.S.G. § 8C2.5(a) (Nov. 1, 2001);

- (2) Add three (3) points pursuant to U.S.S.G. §§ 8C2.5(b)(3)(B)(i), 8C2.5(b)(3)(B)(ii) (Nov. 1, 2001), in that the unit of the organization within which the offense was committed had 200 or more employees, the organization had less than 1,000 employees, an individual within the high-level personnel of the unit participated in and condoned the offenses, and tolerance of the offenses by the substantial authority personnel was pervasive throughout the unit;
  - (3) Deduct two (2) points pursuant to U.S.S.G. § 8C2.5(g)(2) (Nov. 1, 2001).
  - (4) Total culpability score is 6.
- ii. Pursuant to U.S.S.G. § 8C2.6 (Nov. 1, 2001), the appropriate multiplier range associated with a culpability score of 6 is 1.2 to 2.4.
- d. Guideline Fine Range: \$136,935,600 - \$273,871,200
- i. Minimum guideline fine is \$136,935,600, determined pursuant to U.S.S.G. § 8C2.7(a) (Nov. 1, 2001) by multiplying \$114,113,000 by 1.2.
  - ii. Maximum guideline fine is \$273,871,200, determined pursuant to U.S.S.G. § 8C2.7(b) (Nov. 1, 2001) by multiplying \$114,113,000 by 2.4.
- e. The parties agree that (1) disgorgement pursuant to U.S.S.G. § 8C2.9 is not necessary, (2) there is no basis for a downward departure under the U.S.S.G. and (3) that a fine within the guideline range will result in a reasonable sentence taking into consideration all of the factors set forth in 18 U.S.C. §§ 3553(a), 3572.

#### 4. Agreed Disposition

The United States and Serono Labs agree pursuant to Fed. R. Crim. P. 11(c)(1)(C) that the following sentence is the appropriate disposition of the Information:

- a. a criminal fine in the amount of one hundred thirty-six million nine hundred thirty-six thousand dollars (\$136,936,000.) to be paid within one week of the date of sentencing; and
- b. a mandatory special assessment of \$800 (\$400 per count) pursuant to 18 U.S.C. § 3013, which shall be paid to the Clerk of Court on or before the date of sentencing;
- c. In light of the pending civil actions, *United States ex rel. Driscoll v. Serono Inc., et al.*, C.A. No. 00-CV-11680-GAO (D. Mass.); *United States ex rel. Garcia v.*

*Serono, Inc.*, C.A. No. 03-CV-11892-GAO (D. Mass.); *United States ex rel. Boucher, et al v. Serono Laboratories, Inc., et al.*, C.A. No. 05-CV-10722 (RWZ)(D. Mass.) and *United States ex. rel. AIDS Healthcare Foundation v. Serono, Inc.*, C. A. No. 04-12104-GAO (D. Mass.)(the “Civil Actions”) and the Civil Settlement Agreement between Serono Labs and others and the United States relating to the civil actions which are being signed contemporaneously with this plea agreement, and attached hereto as Exhibit B, which requires the payment of \$567,065,000, plus interest, the parties agree that the determination of complex issues of fact related to the cause and the amount of each and every victim's loss would complicate and prolong the sentencing process to a degree that the need to provide restitution to all victims is outweighed by the burden on the sentencing process, especially where, as here, approximately 90% of the losses suffered in this case were sustained by the federal government and state Medicaid agencies, who will be fully recompensed from amounts paid as part of the Civil Settlement Agreement. *See*, 18 U.S.C. § 3663A(c)(3)(B). Therefore, the United States agrees that it will not seek a separate restitution order as to Serono Labs as part of the resolution of the Information and the Parties agree that the appropriate disposition of this case does not include a restitution order.

The United States may, at its sole option, be released from its commitments under this Agreement, including, but not limited to, its agreement in this paragraph regarding the appropriate disposition of this case, if at any time between its execution of this Agreement and sentencing, Serono Labs:

- i. Fails to admit a complete factual basis for the plea;
- ii. Fails to truthfully admit its conduct in the offense of conviction;
- iii. Falsely denies, or frivolously contests, relevant conduct for which Serono Labs is accountable under U.S.S.G. § 1B1.3;
- iv. Gives false or misleading testimony in any proceeding relating to the criminal conduct charged in this case and any relevant conduct for which Serono Labs is accountable under U.S.S.G. § 1B1.3;
- v. Engages in acts which form a basis for finding that Serono Labs has obstructed or impeded the administration of justice under U.S.S.G. § 3C1.1; and/or
- vi. Attempts to withdraw its plea.

Serono Labs expressly understands that it may not withdraw its plea of guilty, unless the Court rejects this Agreement under Fed. R. Crim. P. 11(c)(5).

5. No Further Prosecution of Serono Labs

Pursuant to Fed. R. Crim. P. 11(c)(1)(A), the United States agrees that, other than the charges in the attached Information, it shall not further prosecute Serono Labs for conduct which (a) falls within the scope of the Information; (b) was the subject of the investigation by the grand jury; or (c) was known to the U.S. Attorney prior to the date of execution of this agreement.

This declination is contingent on (a) the guilty plea of Serono Labs being accepted by the Court and not withdrawn, and (b) Serono Labs' performance of all of its obligations as set forth in this Agreement and the attached Civil Settlement Agreement. If Serono Labs' guilty plea is not accepted by the court or is withdrawn for any reason, or if Serono Labs should fail to perform an obligation under this Agreement or the Civil Settlement Agreement, this declination of prosecution shall be null and void.

The United States expressly reserves the right to prosecute any individual, including but not limited to current and former officers, directors, employees, and agents of Serono Labs, in connection with the conduct encompassed by this plea agreement, within the scope of the grand jury investigation, or known to the U.S. Attorney.

6. Payment of Mandatory Special Assessment

Serono Labs agrees to pay the mandatory special assessment to the Clerk of Court on or before the date of sentencing.

7. Cooperation

Serono Labs 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 Labs 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 Labs 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 Labs 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 Labs is not required to take any action against its officers, directors, employees and agents for following their attorney's advice.

In addition, Serono Labs 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 Labs 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 Labs in the U.S. Attorney's ongoing investigation and prosecution.

8. Probation Department Not Bound By Agreement

The sentencing disposition agreed upon by the parties and their respective calculations under the Sentencing Guidelines are not binding upon the United States Probation Office.

9. Fed. R. Crim. P. 11(c)(1)(C) Agreement

Serono Labs' plea will be tendered pursuant to Fed. R. Crim. P. 11(c)(1)(C). Serono Labs cannot withdraw its plea of guilty unless the sentencing judge rejects this Agreement or fails to impose a sentence consistent herewith. If the sentencing judge rejects this Agreement or fails to impose a sentence consistent herewith, this Agreement shall be null and void at the option of either the United States or Serono Labs.

Serono Labs may seek sentencing by the District Court immediately following the Rule 11 plea hearing. The United States does not object to the Court proceeding to sentence Serono Labs immediately following the Rule 11 plea hearing or in the absence of a Presentence Report in this case. Serono Labs understands that the decision whether to proceed immediately following the plea hearing with the sentencing proceeding, and to do so without a Presentence Report, is exclusively that of the United States District Court.

10. Civil and Administrative Liability

By entering into this Agreement, the United States does not compromise any civil or administrative liability, including but not limited to any False Claims Act or tax liability which Serono Labs may have incurred or may incur as a result of its conduct and its plea of guilty to the attached Information.

Serono Labs' civil liability to the United States in connection with certain of the matters under investigation by the United States is resolved in the Civil Settlement Agreement, attached as Exhibit B, according to the terms set forth in that Agreement.

11. Waiver of Defenses

If Serono Labs' guilty plea is not accepted by the Court for whatever reason, or is later withdrawn for whatever reason, Serono Labs hereby waives, and agrees it will not interpose, if charges are filed within six months of the date on which such guilty plea is rejected or withdrawn, any defense to any charges brought against it which it might otherwise have under

the Constitution, any statute of limitations, or the Speedy Trial Act, except any such defense that Serono Labs may already have for conduct occurring before December 1, 1998.

12. Breach of Agreement

If the U.S. Attorney determines that Serono Labs has failed to comply with any material provision of this Agreement, the United States may, at its sole option, be released from its commitments under this Agreement in its entirety by notifying Serono Labs, through counsel or otherwise, in writing. The United States may also pursue all remedies available under the law, even if it elects not to be released from its commitments under this Agreement. Serono Labs recognizes that no such breach by Serono Labs of a material obligation under this Agreement shall be grounds for withdrawal of its guilty plea. Serono Labs understands that should it breach any material provision of this Agreement, the U.S. Attorney will have the right to use against Serono Labs before any grand jury, at any trial or hearing, or for sentencing purposes, any statements that may be made by Serono Labs, and any information, materials, documents or objects which may be provided by it to the government subsequent to this Agreement, without any limitation.

Serono Labs understands and agrees that this 11(c)(1)(C) plea agreement and its agreed upon criminal disposition:

- a. are wholly dependent upon Serono Labs' timely compliance with the material provisions of the attached Civil Settlement Agreement, including the requirement in the agreement that Serono Labs or an affiliate pay to the United States and to the various state Medicaid Programs the amount of five hundred sixty seven million sixty-five thousand dollars (\$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 in accord with the terms of the Civil Settlement Agreement; and that
- b. failure by Serono Labs to comply fully with the material terms of this Agreement or the attached Civil Settlement Agreement will constitute a breach of this Agreement, provided however, that a breach of the Corporate Integrity Agreement and Addendum thereto (collectively "CIA"), incorporated by reference in the Civil Settlement Agreement, does not constitute a breach of this Plea Agreement, and any disputes arising under the CIA shall be resolved exclusively through the dispute resolution provisions of the CIA.

In the event Serono Labs at any time hereafter breaches any material provision of this Agreement, Serono Labs understands that (1) the United States will as of the date of that breach be relieved of any obligations it may have in this Agreement and the attached Civil Settlement Agreement, including but not limited to the promise not to further prosecute Serono Labs as set forth in paragraph 5 of this Agreement; and (2) Serono Labs will not be relieved of its obligation to make the payments set forth in this Agreement and the attached Civil Settlement Agreement, nor will it be entitled to return of any monies already paid. Moreover, in the event of a breach,

Serono Labs hereby waives, and agrees it will not interpose, any defense to any additional charges brought against it which it might otherwise have under any statute of limitations, or the Speedy Trial Act, except any such defense that Serono Labs may already have for conduct occurring before December 1, 1998.

13. Corporate Authorization

Serono Labs' acknowledgment of this Agreement and execution of this Agreement on behalf of the corporation is attached as Exhibit C. Serono Labs shall provide to the U.S. Attorney and the Court a certified copy of a resolution of the Board of Directors of Serono Laboratories, Inc., affirming that the Board of Directors has authority to enter into the Plea Agreement and has (a) reviewed the Information in this case and the proposed Plea Agreement; (b) consulted with legal counsel in connection with the matter; (c) voted to enter into the proposed Plea Agreement; (d) voted to authorize Serono Labs to plead guilty to the charges specified in the Information; and (e) voted to authorize the corporate officer identified below to execute the Plea Agreement and all other documents necessary to carry out the provisions of the Plea Agreement. A copy of the resolution is attached as Exhibit D. Serono Labs agrees that either a duly authorized corporate officer or a duly authorized attorney for Serono Labs, at the discretion of the Court, shall appear on behalf of Serono Labs and enter the guilty plea and will also appear for the imposition of sentence.

14. Who Is Bound By Agreement

This Agreement is binding upon Serono Labs and the Attorney General of the United States, the United States Department of Justice, and all United States Attorneys on the matters set forth above in Paragraph 5, but does not bind the Tax Division of the U.S. Department of Justice or the Internal Revenue Service of the U.S. Department of the Treasury. A copy of the letter to United States Attorney Michael Sullivan from Alice Fisher, Assistant Attorney General, Criminal Division, Department of Justice, authorizing this Agreement is attached as Exhibit E. Serono Labs understands that this Agreement does not bind any state or local prosecutive authorities.

15. Complete Agreement

This Agreement, together with the Civil Settlement Agreement, set forth the complete and only agreement between the Parties relating to the disposition of this matter. No promises, representations, agreements or conditions have been entered into other than those set forth in this letter and its attachments A through E. This agreement supersedes prior understandings, if any, of the parties, whether written or oral. This agreement can be modified or supplemented only in a written memorandum signed by the Parties or as agreed by the Parties on the record in court.

If this letter accurately reflects the Agreement entered into between the United States and your client Serono Laboratories, Inc., please have the authorized representative of Serono Labs sign the Acknowledgment of Agreement below. Please also sign as Witness. Return the original

of this letter to Assistant U.S. Attorney Mary Elizabeth Carmody of the United States Attorney's Office of the District of Massachusetts.

Very truly yours,

By: \_\_\_\_\_  
MICHAEL J. SULLIVAN  
United States Attorney  
District of Massachusetts

By: \_\_\_\_\_  
MARY ELIZABETH CARMODY  
Assistant U.S. Attorney  
District of Massachusetts

**ACKNOWLEDGMENT OF AGREEMENT**

The Board of Directors has authorized me to execute this Plea Agreement and attached Civil Settlement Agreement on behalf of Serono Laboratories, Inc. The Board has read this Plea Agreement, the attached criminal Information, and the Civil Settlement Agreement including its attachment in their entirety and has discussed them fully in consultation with Serono Laboratories, Inc.'s attorney. The Board acknowledges that these documents fully set forth Serono Laboratories, Inc.'s agreement with the United States. The Board further states that no additional promises or representations have been made to Serono Laboratories, Inc., by any officials of the United States in connection with the disposition of this matter, other than those set forth in the Plea Agreement and the attached Civil Settlement Agreement.

Dated:

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

Dated:

\_\_\_\_\_  
HENRY DEPIPPA, ESQUIRE  
Nixon Peabody LLP  
Counsel for Serono Laboratories, Inc.

Dated:

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MELISSA TEARNEY  
Nixon Peabody LLP  
Counsel for Serono Laboratories, Inc.