

SETTLEMENT AGREEMENT

This Settlement Agreement (“Agreement”) is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General (“OIG-HHS”) of the Department of Health and Human Services (“HHS”) (collectively, the “United States”), Nostrum Laboratories, Inc. (“Nostrum”) and Nirmal Mulye, Ph.D. (“Mulye”) (hereafter all collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

A. In order to obtain federal reimbursement for its covered outpatient drugs under any state Medicaid programs, *see* 42 U.S.C. §§ 1396-1396w-5 (“Medicaid”), all of which the federal government jointly finances with the states, a pharmaceutical manufacturer must opt into the Medicaid Drug Rebate Program (“MDRP”). The MDRP’s implementing statute, 42 U.S.C. § 1396r-8 (the “Rebate Statute”), requires such manufacturers to enter into a rebate agreement. On or about August 16, 2016, Nostrum entered into a rebate agreement (“Rebate Agreement”) with HHS. The Rebate Statute and implementing regulations set forth certain terms of the Rebate Agreement. *See* 42 C.F.R. § 447.510. The Rebate Statute and Rebate Agreement require, among other things, the manufacturer to pay to each state Medicaid program a quarterly amount that potentially includes an inflation-adjusted “additional rebate” for each “dosage form and strength” of a covered outpatient drug. *See* 42 U.S.C. § 1396r-8(c)(2)(A). For example, for “a covered outpatient drug that is first marketed as a drug other than a single source drug or an innovator multiple source drug after April 1, 2013,” manufacturers must also pay an inflation-based rebate equaling the difference, if any, between the drug’s current quarter AMP and its AMP in the “applicable quarter” (which is defined as the “fifth full calendar quarter after which the drug is first marketed”) adjusted by the rate of inflation. 42 U.S.C. § 1396r-8(c)(3). The

AMP that serves as the starting point for the “additional rebate” calculation is commonly called the “Base Date AMP,” and the quarter with which that price is associated is referred to as the “Base Date AMP” quarter. The Rebate Agreement requires manufacturers to make the proper rebate payments “not later than 30 days after receiving the state rebate invoice” and also requires manufacturers to “comply with the conditions of the [Rebate Statute], changes thereto, implementing regulations, agency guidance, and [the Rebate Agreement].”

B. Nostrum is a privately held New Jersey corporation with its principal places of business in Missouri and New Jersey and an office in New York that does business as a pharmaceutical manufacturer and markets Nitrofurantoin Oral Suspension in the United States under Abbreviated New Drug Application (“ANDA”) number 201355 (“Nitro OS”). Nitro OS is an oral suspension antibacterial agent. At all relevant times herein, Nostrum had entered into a Rebate Agreement with the HHS.

C. Another manufacturer secured the FDA approval for Nitro OS in August 2013 and began to market it in January 2014. Nostrum then acquired exclusive rights to manufacture and market Nitro OS in 2015. At all relevant times, Nostrum sold Nitro OS under National Drug Code (“NDC”) number 70408-239-32 and marketed it under ANDA number 201355. Nitro OS is a “noninnovator multiple source drug” for purposes of the Medicaid Rebate Program.

D. Mulye is the founder and chief executive officer of Nostrum. Mulye maintains ultimate control of Nostrum and, either directly or through other entities he is the sole owner of, and maintains a 90 percent ownership interest in Nostrum.

E. The United States contends (1) that Nostrum and Mulye submitted or caused to be submitted claims for payment to Medicaid for Nitro OS; (2) that Nostrum entered into a Rebate Agreement with the Secretary of HHS in exchange for Medicaid’s coverage of Nitro OS; (3) that Nostrum, under the Rebate Agreement and Rebate Statute, was required to submit pricing

information on a quarterly basis to the Centers for Medicare and Medicaid Services (“CMS”) regarding Nitro OS and pay the correct quarterly rebates to state Medicaid programs per unit of Nitro OS dispensed to Medicaid beneficiaries, as determined by the statutory formula set forth in the Rebate Statute, and based on which rebate invoices are sent by State Medicaid programs to Nostrum.

F. The United States contends that it has certain civil claims against Nostrum and Mulye from October 1, 2018 through March 31, 2020 for failing to pay the required rebate amounts owed for Nitro OS as required by the Rebate Statute and Rebate Agreement and as invoiced by State Medicaid programs.

G. Nostrum and Mulye admit, acknowledge, and accept their responsibility for the following facts:

Nostrum acquired Nitro OS from another manufacturer in December 2015 and continued to market the product pursuant to Nitro OS’s preexisting FDA approval, ANDA Number 201355. In response to January 2018 FDA updated guidance tightening tolerances for elemental impurities in various drug products, Nostrum ceased manufacturing and marketing Nitro OS temporarily because the amount of lead in Nitro OS, resulting from Nostrum’s formulation at the time, did not comply with the 2018 FDA guidance. Nostrum resumed manufacturing and marketing Nitro OS in August 2018, after having adjusted its Nitro OS formulation to address the new FDA impurities guidance by reducing lead levels and modifying quantities of two inactive ingredients. Nostrum has characterized the relaunched version of Nitro OS as a “reformulation.” Nostrum did not add or subtract any ingredients and the active ingredients remain unchanged; Nitro OS also remained in the same dosage form and strength as it did prior to 2018. Nostrum continues to market this newer version of Nitro OS under the same FDA

Approval, ANDA 201355, as the pre-2018 version and maintains with FDA that it is legal to do so because no major changes have been made to the drug.

After relaunching Nitro OS in August 2018, Nostrum increased its price from \$474.75 to \$2,392.32 per bottle. Beginning with the third quarter of 2018, Nostrum received invoices from state Medicaid Programs reflecting significantly increased Medicaid rebates owed. Based on its later investigation, Nostrum found out that these larger rebate invoices were on account of the Nitro OS price increase triggering the inflation based Medicaid rebate. Nostrum paid these increased rebates as invoiced by the states for the third quarter of 2018. Thereafter, Nostrum and Mulye did not pay the entire amount of the invoiced amounts due, which included amounts that accounted for the price increase. Nostrum wrote to CMS arguing that it should not have to pay the inflation-based amount because its Nitro OS is a “new” drug after its 2018 relaunch and, therefore, should not have to pay rebates based upon the “old” version of Nitro OS’s 2015 Base Date AMP. In a subsequent teleconference and in correspondence with CMS personnel, including the director of the pertinent CMS division, Nostrum and Mulye understood that: 1) CMS did not agree with Nostrum’s position; and 2) that CMS’s position was that Nostrum should pay its calculated rebate amount going forward, based upon the Q2 2015 Base Date AMP, and that Nostrum should repay any underpayments so far. Nostrum did not and instead chose to terminate the applicable Rebate Agreement, effective March 30, 2020, with partial balances due for Q4 2018 through Q1 2020. The foregoing conduct in Recitals F-G is hereinafter referred to as the “Covered Conduct.”

H. Nostrum admits and agrees that the correct Base Date AMP Quarter for Nitro OS is Q2 2015 and that, accordingly, the correct Base Date AMP for Nitro OS is Nitro OS’s AMP from Q2 2015.

I. Nostrum and Mulye will enter into separate settlement agreements (hereinafter referred to as the “Medicaid State Settlement Agreements”) with certain states, which for the purposes of this agreement includes the District of Columbia, in settlement of the conduct released in those separate Medicaid State Settlement Agreements. States with which Nostrum and Mulye execute a Medicaid State Settlement Agreement in the form to which they and the States have agreed through a State Negotiating Team, or in a form otherwise agreed to by them and an individual State, shall be defined as “Medicaid Participating States.”

In consideration of the mutual promises and obligations of this Settlement Agreement, and for other good and valuable consideration, the receipt and sufficient of which are hereby acknowledged, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Nostrum and Mulye shall make total payments to the United States and the Medicaid Participating States, collectively, of three million eight hundred twenty-five thousand dollars (\$3,825,000), as specified in paragraphs 1(a) and 1(b) below (“Total Fixed Settlement Amount”). In addition, Nostrum shall make any payments due under subparagraphs 1(a)(i)-(iv) and Mulye shall make any payments due under subparagraphs 1(b)(i)-(iii) (collectively, “Contingency Payments”). However, no further Contingency Payments from either Nostrum or Mulye are due once the Total Fixed Settlement Amount paid plus any Contingency Payments paid exceed fifty million dollars (\$50,000,000).

(a) Nostrum shall pay to the United States and the Medicaid Participating States collectively two million three hundred twenty-five thousand dollars (\$2,325,000) in nine installments pursuant to the payment schedule described in Exhibit A. (“Nostrum Fixed Settlement Amount”). Of the Nostrum Fixed Settlement Amount due pursuant to the payment schedule described in Exhibit A, Nostrum shall pay a total of one million

two hundred thirty-two thousand two hundred fifty dollars (\$1,232,250) to the United States, (collectively the “Nostrum Federal Fixed Settlement Amount”) by electronic funds transfer pursuant to written instructions to be provided by the Office of the United States Attorney for the District of Massachusetts, and Nostrum shall pay a total of one million ninety-two thousand seven hundred fifty dollars (\$1,092,750) to the Medicaid Participating States pursuant to the terms of the Medicaid State Settlement Agreements (“Nostrum State Fixed Settlement Amount”). In addition to the Nostrum Fixed Settlement Amount, Nostrum shall make any additional payments as required by subparagraphs (i) through (iv) below (“Nostrum Contingency Payments”), collectively, to the United States and Medicaid Participating States, divided on the same pro-rata basis as the Nostrum Fixed Settlement Amount is divided between the Nostrum Federal Fixed Settlement Amount and Nostrum State Fixed Settlement Amount and using the same payment method. The Nostrum Fixed Settlement Amount plus any Nostrum Contingency Payments due are hereinafter referred to as the “Nostrum Settlement Amount.”

(i) If, in any of the first five (5) full years that conclude following the Effective Date of this Settlement Agreement (each year of which is a “Measurement Period”), Nostrum achieves earnings before interest, taxes, depreciation, and amortization for such Measurement Period as set forth in its annual financial statements prepared on an audited basis by independent certified public accountants selected by Nostrum (“EBITDA”), Nostrum shall pay the United States and the Medicaid Participating States, collectively, an amount equal to five percent (5.0%) of its EBITDA for such Measurement Period (each referred to as a “Performance Contingency Payment”). Within one hundred twenty (120)

days of the end of each Measurement Period, Nostrum shall submit to the Department of Justice, Civil Division, annual audited financial statements and a calculation of the EBITDA and any Performance Contingency Payment Amount (“Annual Financials”). The calculation of EBITDA and Performance Contingency Payment shall be certified as true and accurate by Nostrum’s Chief Executive Officer and Chief Financial Officer. Nostrum shall pay any owed Performance Contingency Payments within one hundred fifty (150) days of the end of each Measurement Period.

(ii) Nostrum agrees to provide fifteen (15) business days advance, written notice to the United States of any sale, transfer, merger, or liquidation of any Nostrum assets or any other property, entity, or venture in which Nostrum has an ownership interest in excess of \$10 million, except its pharmaceutical products sold in the ordinary course of its business, in any of the first five full years that conclude after the Effective Date (“Sale Event”). Upon the occurrence of a Sale Event and within seven (7) business days of the closing on the Sale Event, Nostrum shall pay the United States and the Medicaid Participating States, collectively, an amount equal to ten percent (10%) of the net proceeds generated from the Sale Event (“Sale Contingency Payment”).

(iii) Nostrum shall pay the United States and the Medicaid Participating States, collectively, an amount equal to fifty percent (50%) of any repayment Nostrum receives, within the five years of the Effective Date of this Agreement, of a loan Nostrum issued to Asia Pacific Investment Holdings Limited (“Asia Pacific”), an affiliate of Nalinkant Rathod (“Loan Contingency Payment”).

Nostrum shall make any Loan Contingency Payment within ten (10) business days of the date upon which it receives any repayment on the Asia Pacific loan.

(iv) Nostrum shall pay to the United States and Medicaid Participating States, collectively, twenty-five percent (25%) of the amount of any payment from any insurance coverage, policy, plan, or claim Nostrum receives within five years of the Effective Date of this Agreement relating to the substance of litigation, disputes, or claims relating to the Covered Conduct or the government's investigation relating thereto (excluding coverage for legal fees and expenses).

(b) Mulye shall pay to the United States and the Medicaid Participating States collectively one million five hundred thousand dollars (\$1,500,000) in nine installments pursuant to the payment schedule described in Exhibit B. ("Mulye Fixed Settlement Amount"). Of the Mulye Fixed Settlement Amount due pursuant to the payment schedule described in Exhibit B, Mulye shall pay a total of seven hundred ninety-five thousand dollars (\$795,000) to the United States (collectively the "Mulye Federal Fixed Settlement Amount") by electronic funds transfer pursuant to written instructions to be provided by the Office of the United States Attorney for the District of Massachusetts, and Mulye shall pay a total of seven hundred five thousand dollars (\$705,000) to the Medicaid Participating States pursuant to the terms of the Medicaid State Settlement Agreements ("Mulye State Fixed Settlement Amount"). In addition to the Mulye Fixed Settlement Amount, Mulye shall make any additional payments as required by subparagraphs (i) through (iii) below ("Mulye Contingency Payments"), collectively, to the United States and Medicaid Participating States, divided on the same pro-rata basis as the Nostrum Fixed Settlement Amount is divided between the Nostrum Federal Fixed Settlement Amount and Nostrum State Fixed Settlement Amount and using the same

payment method. The Mulye Fixed Settlement Amount plus any Mulye Contingency Payments due are hereinafter referred to as the “Mulye Settlement Amount.”

(i) Mulye shall pay to the United States and the Medicaid Participating States, collectively, any payments or 1099 income received from the government as specified in a letter from counsel for the United States to counsel for Mulye dated October 24, 2023, within fourteen (14) days of receiving any such funds.

(ii) Mulye shall pay the United States and the Medicaid Participating States, collectively, an amount equal to fifty percent (50%) of any repayment Mulye receives, within the five years of the Effective Date of this Agreement, of a loan Nostrum issued to Asia Pacific (“Loan Contingency Payment”). Mulye shall make any Loan Contingency Payment within ten (10) business days of the date upon which he receives any repayment on the Asia Pacific loan.

(iii) Mulye shall pay to the United States and Medicaid Participating States, collectively, twenty-five percent (25%) of the amount of any payment from any insurance coverage, policy, plan, or claim Mulye receives within five years of the Effective Date of this Agreement relating to the substance of litigation, disputes, or claims relating to the Covered Conduct or the government’s investigation relating thereto (excluding coverage for legal fees and expenses).

2. The Nostrum Federal Fixed Settlement Amount and the Mulye Federal Fixed Settlement Amount are considered restitution to the United States. The Nostrum State Fixed Settlement Amount and the Mulye State Fixed Settlement Amount are considered restitution to the Medicaid Participating States.

3. Subject to the exceptions in Paragraph 5 (concerning reserved claims) below, and subject to Paragraph 6 (concerning disclosure of assets), Paragraph 13 (concerning default), and Paragraph 14 (concerning bankruptcy) below, and upon the United States' receipt of the Nostrum Federal Settlement Amount, the United States releases Nostrum, together with its current and former parent corporations or entities; direct and indirect subsidiaries; and brother or sister corporations or entities; and their respective divisions, current or former corporate owners; and the corporate or entity successors and assigns of any of them, from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of payment by mistake, unjust enrichment, and fraud.

4. Subject to the exceptions in Paragraph 5 (concerning reserved claims) below, and subject to Paragraph 6 (concerning disclosure of assets), Paragraph 13 (concerning default), and Paragraph 14 (concerning bankruptcy) below, and upon the United States' receipt of the Mulye Federal Settlement Amount, the United States releases Nirmal Mulye from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of payment by mistake, unjust enrichment, and fraud.

5. Notwithstanding the releases given in Paragraphs 3 and 4 of this Agreement, or any other term of this Agreement, the following claims and rights of the United States are specifically reserved and are not released:

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;

- c. Except as explicitly stated in this Agreement, any administrative liability or enforcement right, including mandatory or permissive exclusion from Federal health care programs;
- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon obligations created by this Agreement;
- f. Except for Nirmal Mulye, any liability of individuals;
- g. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- h. Any liability for failure to deliver goods or services due; and
- i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

6. Nostrum and Mulye each have provided sworn financial disclosures and supporting documents (together “Financial Disclosures”) to the United States and the United States has relied on the accuracy and completeness of those Financial Disclosures in reaching this Agreement. Nostrum and Mulye each warrant that their Financial Disclosures are complete, accurate, and current as of the date provided. If the United States learns of asset(s) in which Nostrum or Mulye had an interest of any kind as of the Effective Date of this Agreement (including, but not limited to, promises by insurers or other third parties to satisfy Nostrum or Mulye’s obligations under this Agreement) that were not disclosed in the Financial Disclosures, or if the United States learns of any false statement or misrepresentation by Nostrum or Mulye on, or in connection with, the Financial Disclosures, and if such nondisclosure, false statement, or misrepresentation changes the estimated net worth set forth in the Financial Disclosures by

\$500,000 or more, the United States may at its option: (a) rescind this Agreement and file suit based on the Covered Conduct or (b) collect the full Settlement Amount in accordance with the Agreement plus one hundred percent (100%) of the net value of Nostrum's or Mulye's previously undisclosed assets. Nostrum and Mulye agree not to contest any collection action undertaken by the United States pursuant to this provision, and agree that they will immediately pay the United States the greater of (i) a ten-percent (10%) surcharge of the amount collected in the collection action, as allowed by 28 U.S.C. § 3011(a), or (ii) the United States' reasonable attorneys' fees and expenses incurred in such an action. In the event that the United States, pursuant to this paragraph rescinds this Agreement, Nostrum and Mulye waive and agree not to plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any civil or administrative claims that (a) are filed by the United States within 120 calendar days of written notification to Nostrum and/or Mulye that this Agreement has been rescinded, and (b) relate to the Covered Conduct, except to the extent these defenses were available on the Effective Date of this Agreement.

7. Nostrum and Mulye each waive and shall 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.

8. Nostrum and Mulye each fully and finally release the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that they have asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees,

and servants, related to the Covered Conduct or the United States' investigation or prosecution thereof.

9. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, carrier or any state payer), related to the Covered Conduct; and Nostrum and Mulye agree not to resubmit to any Medicare contractor or any state payer any previously denied claims related to the Covered Conduct, agree not to appeal any such denials of claims, and agree to withdraw any such pending appeals.

10. Nostrum and Mulye each agree to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395lll and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Nostrum and Mulye, their present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement;
- (2) the United States' audit(s) and civil investigation(s) of the matters covered by this Agreement;
- (3) Nostrum and Mulye's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation(s) in connection with the matters covered by this Agreement (including attorneys' fees);
- (4) the negotiation and performance of this Agreement; and

- (5) the payments Nostrum and Mulye make to the United States pursuant to this Agreement.

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Nostrum and Mulye, and they shall 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 or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Nostrum and Mulye further agree that within 90 days of the Effective Date of this Agreement they shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid 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 Nostrum and Mulye or any of their subsidiaries or affiliates, and shall 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. Nostrum and Mulye agree that the United States, at a minimum, shall be entitled to recoup from them any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments 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 Nostrum and Mulye or any of their subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on Nostrum's and Mulye's or any of their subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Nostrum's and Mulye's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this paragraph.

11. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraphs 3, 4 and 8 and Paragraph 12 (waiver for beneficiaries paragraph), below.

12. Nostrum and Mulye agree that they waive and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

13. The Total Fixed Settlement Amount represents the amount the United States is willing to accept in compromise of its civil claims arising from the Covered Conduct due solely to Nostrum and Mulye's financial condition as reflected in the Financial Disclosures referenced in Paragraph 6.

a. In the event that Nostrum fails to pay any portion of the Nostrum Settlement Amount or in the event that Mulye fails to pay any portion of the Mulye Settlement Amount, the party failing to make such payment ("Defaulting Party") shall be in default of their payment

obligations under this Agreement (“Default”). The United States will provide a written Notice of Default, and the Defaulting Party shall have an opportunity to cure such Default within fourteen (14) days from the date of receipt of the Notice of Default by making the payment due under the payment schedule. Notice of Default will be delivered to Defaulting Party, or to such other representative as Defaulting Party shall designate in advance in writing. If Defaulting Party fails to cure the Default within fourteen (14) calendar days of receiving the Notice of Default and in the absence of an agreement with the United States to a modified payment schedule (“Uncured Default”), the remaining unpaid balance of the Settlement Amount shall become immediately due and payable subject to and in accordance with their respective terms, and interest on the remaining unpaid balance shall thereafter accrue at the rate of five percent (5%) per annum, compounded daily from the date of Default, on the remaining unpaid total (principal and interest balance).

b. In the event of Uncured Default, the Defaulting Party agrees that the United States, at its sole discretion, may (i) retain any payments previously made, rescind this Agreement, or bring any civil and/or administrative claim, action, or proceeding against the Defaulting Party for the claims that would otherwise be covered by the releases provided in Paragraph 3 and 4 above, with any recovery reduced by the amount of any payments previously made by Defaulting Party to the United States under this Agreement; (ii) take any action to enforce this Agreement; (iii) offset the remaining unpaid balance from any amounts due and owing to Defaulting Party and/or affiliated companies by any department, agency, or agent of the United States at the time of Default or subsequently; and/or (iv) exercise any other right granted by law, or under the terms of this Agreement, or recognizable at common law or in equity. The United States shall be entitled to any other rights granted by law or in equity by reason of Default, including referral of this matter for private collection. In the event the United States

pursues a collection action, the Defaulting Party agrees immediately to pay the United States the greater of (i) a ten-percent (10%) surcharge of the amount collected, as allowed by 28 U.S.C. § 3011(a), or (ii) the United States' reasonable attorneys' fees and expenses incurred in such an action. In the event that the United States opts to rescind this Agreement pursuant to this paragraph, Nostrum and Mulye waive and agree not to plead, argue, or otherwise raise any defenses of statute of limitations, laches, estoppel or similar theories, to any civil or administrative claims that are (i) filed by the United States against Nostrum and Mulye within 120 days of written notification that this Agreement has been rescinded, and (ii) relate to the Covered Conduct, except to the extent these defenses were available on the Effective Date of the Agreement. Nostrum and Mulye agree not to contest any offset, recoupment, and /or collection action undertaken by the United States pursuant to this paragraph, either administratively or in any state or federal court, except on the grounds of actual payment to the United States.

c. In the event of Uncured Default, OIG-HHS may exclude the Defaulting Party from participating in all Federal health care programs until Defaulting Party pays the Settlement Amount, with interest, as set forth above (Exclusion for Default). OIG-HHS will provide written notice of any such exclusion to Defaulting Party. The Defaulting Party waives any further notice of the exclusion under 42 U.S.C. § 1320a-7(b)(7), and agrees not to contest such exclusion either administratively or in any state or federal court. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, Defaulting Party wishes to apply for reinstatement, it must submit a written request for reinstatement to OIG-HHS in accordance with the provisions of 42 C.F.R. §§ 1001.3001-.3005. Defaulting Party will not be reinstated unless and until OIG-HHS approves such request for reinstatement. The option for Exclusion for Default is in addition to, and not in lieu of, the options identified in this Agreement or otherwise available.

14. In exchange for valuable consideration provided in this Agreement, Nostrum and Mulye acknowledge the following:

a. Nostrum and Mulye have each reviewed their financial situation and warrants that they are solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I) and shall remain solvent following payment to the United States of the Settlement Amount.

b. In evaluating whether to execute this Agreement, the Parties intend that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to Nostrum and Mulye, within the meaning of 11 U.S.C. § 547(c)(1), and the Parties conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange.

c. The mutual promises, covenants, and obligations set forth herein are intended by the Parties to, and do in fact, constitute a reasonably equivalent exchange of value.

d. The Parties do not intend to hinder, delay, or defraud any entity to which Nostrum and Mulye were or became indebted to on or after the date of any transfer contemplated in this Agreement, within the meaning of 11 U.S.C. § 548(a)(1).

e. If any of Nostrum's or Mulye's payments or obligations under this Agreement are avoided for any reason (including but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code) or if, before the applicable Total Fixed Settlement Amount is paid in full, Nostrum or Mulye or a third party commences a case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors seeking any order for relief of Nostrum's or Mulye's debts, or to adjudicate Nostrum or Mulye as bankrupt or insolvent; or an Order is entered appointing a receiver, trustee, custodian, or other similar official for Nostrum or Mulye or for all or any substantial part of Nostrum's or Mulye's assets (collectively an "Insolvency Proceeding"):

(i) the United States may rescind the releases in this Agreement and bring any civil and/or administrative claim, action, or proceeding against the entity or person to whom subparagraph (e) above applies (the “Avoiding Defendant”) for the claims that would otherwise be covered by the releases provided in Paragraphs 3 and 4 above; and

(ii) in any Insolvency Proceeding in which either 1) court approval to pay the Settlement Amount in full is not sought by Nostrum or Mulye; 2) court approval of such a request is not granted for any reason; 3) the Settlement Amount is not paid in full for any reason; or 4) if assets in which Nostrum or Mulye have an interest, or the assets considered property of any applicable estate for purposes of the Insolvency Proceeding (including any interest in property recovered through any action of any appointed trustee, receiver, examiner, or equivalent) are identified to be greater than total assets disclosed as discussed in Paragraph 6 by more than \$500,000 the United States has at its option an undisputed, noncontingent, and liquidated allowed claim against the Avoided Defendant in the amount of \$50,000,000.00 less any payments received pursuant to Paragraph 1 of this Agreement, provided, however, that such payments are not otherwise avoided and recovered from the United States by Nostrum or Mulye, a receiver, trustee, custodian, or other similar official for Nostrum or Mulye.

f. Nostrum and Mulye agree that any civil and/or administrative claim, action, or proceeding brought by the United States under Paragraph 14.e. is not subject to an “automatic stay” pursuant to 11 U.S.C. § 362(a) because it would be an exercise of the United States’ police and regulatory power. Nostrum and Mulye shall not argue or otherwise contend that the United States’ claim, action, or proceeding is subject to an automatic stay and, to the extent necessary, consents to relief from the automatic stay for cause under 11 U.S.C. § 362(d)(1). Nostrum and Mulye waive and shall 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

claim, action, or proceeding brought by the United States within 120 days of written notification to Nostrum and Mulye that the releases have been rescinded pursuant to this paragraph, except to the extent such defenses were available on the Effective Date of the Agreement.

15. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

16. Each Party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

17. This Agreement is governed by the laws of the United States. The exclusive venue for any dispute relating to this Agreement is the United States District Court for the District of Massachusetts. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

18. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties. Forbearance by the United States from pursuing any remedy or relief available to it under this Agreement shall not constitute a waiver of rights under this Agreement.

19. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

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

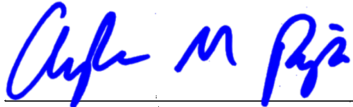
21. This Agreement is binding on Nostrum's and Mulye's successors, transferees, heirs, and assigns.

22. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.


23. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED: 10/27/2023

BY: 
Augustine Ripa
Michael Hoffman
Attorneys
Commercial Litigation Branch
Civil Division

DATED: 10/25/2023

BY: 
Evan Panich
Assistant United States Attorney
District of Massachusetts

DATED: _____

BY: _____
Lisa M. Re
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____

Augustine Ripa
Michael Hoffman
Attorneys
Commercial Litigation Branch
Civil Division

DATED: _____

BY: _____

Evan Panich
Assistant United States Attorney
District of Massachusetts


DATED: _____

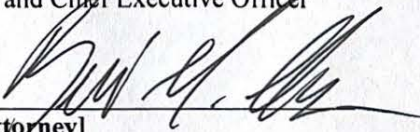
BY: _____

LISA RE  Digitally signed by LISA RE
Date: 2023.10.27 08:32:52
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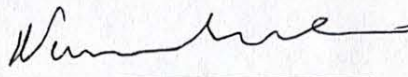
Lisa M. Re
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

NOSTRUM LABORATORIES, INC.

DATED: 10/24/23 BY: 
Nirmal Mulye, Ph.D., Chairman
and Chief Executive Officer

DATED: 10/25/23 BY: 
[Attorney]
Counsel for Nostrum Laboratories, Inc.

NIRMAL MULYE, Ph.D.

DATED: 10/24/23 BY: 
Nirmal Mulye, Ph.D.

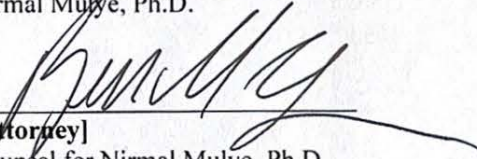
DATED: 10/25/23 BY: 
[Attorney]
Counsel for Nirmal Mulye, Ph.D.

Exhibit A – Nostrum Installment Payment Schedule

Nostrum will pay the Nostrum Fixed Settlement Amount to the United States and the Medicaid Participating States in installments as follows:

- 1) 75,000.00 within 7 days of the Effective Date of this Agreement (“First Installment Payment”), with \$39,750.00 paid to the United States and \$35,250.00 paid to the Medicaid Participating States;
- 2) 75,000.00 within 60 days of the First Installment Payment, with \$39,750.00 paid to the United States and \$35,250.00 paid to the Medicaid Participating States;
- 3) 175,000.00 within 120 days of the First Installment Payment, with \$92,750.00 paid to the United States and \$82,250.00 paid to the Medicaid Participating States;
- 4) 175,000.00 within 180 days of the First Installment Payment, with \$92,750.00 paid to the United States and \$82,250.00 paid to the Medicaid Participating States;
- 5) \$1,070,000.00 within one year of the First Installment Payment, with \$567,100.00 paid to the United States and \$502,900.00 paid to the Medicaid Participating States;
- 6) \$125,000.00 within two years of the First Installment Payment, with \$66,250.00 paid to the United States and \$58,750.00 paid to the Medicaid Participating States;
- 7) \$130,000.00 within three years of the First Installment Payment, with \$68,900.00 paid to the United States and \$61,100.00 paid to the Medicaid Participating States;
- 8) \$250,000.00 within four years of the First Installment Payment, with \$132,500 paid to the United States and \$117,500 paid to the Medicaid Participating States;
- 9) \$250,000.00 within five years of the First Installment Payment, with \$132,500 paid to the United States and \$117,500 paid to the Medicaid Participating States.

Exhibit B – Nirmal Mulye Installment Payment Schedule

Mulye will pay the Mulye Fixed Settlement Amount to the United States and the Medicaid Participating States in installments as follows:

- 1) 25,000.00 within 7 days of the Effective Date of this Agreement (“First Installment Payment”), with \$13,250.00 paid to the United States and \$11,750.00 paid to the Medicaid Participating States;
- 2) 25,000.00 within 60 days of the First Installment Payment, with \$13,250.00 paid to the United States and \$11,750.00 paid to the Medicaid Participating States;
- 3) 75,000.00 within 120 days of the First Installment Payment, with \$39,750.00 paid to the United States and \$35,250.00 paid to the Medicaid Participating States;
- 4) 125,000.00 within 180 days of the First Installment Payment, with \$66,250.00 paid to the United States and \$58,750.00 paid to the Medicaid Participating States;
- 5) \$250,000.00 within one year of the First Installment Payment, with \$132,500 paid to the United States and \$117,500 paid to the Medicaid Participating States;
- 6) \$250,000.00 within two years of the First Installment Payment, with \$132,500 paid to the United States and \$117,500 paid to the Medicaid Participating States;
- 7) \$250,000.00 within three years of the First Installment Payment, with \$132,500 paid to the United States and \$117,500 paid to the Medicaid Participating States;
- 8) \$250,000.00 within four years of the First Installment Payment, with \$132,500 paid to the United States and \$117,500 paid to the Medicaid Participating States;
- 9) \$250,000.00 within five years of the First Installment Payment, with \$132,500 paid to the United States and \$117,500 paid to the Medicaid Participating States.