

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF PUERTO RICO

UNITED STATES OF AMERICA,

Plaintiff,

v.

DROGUERIA BETANCES, LLC,

Defendant.

Civil No. 23-1538

CONSENT DECREE

The United States of America has filed a Complaint for civil penalties against Defendant Droguería Betances, LLC (“Betances”) for violations of the Controlled Substances Act, 21 U.S.C. §§ 801-904 (“CSA” or the “Act”), and its implementing regulations, 21 C.F.R. §§ 1301-1321. The United States and Betances (the “Parties”) stipulate to the entry of this Consent Decree to resolve the claims in the Complaint pursuant to the following terms.

RECITALS

1. Plaintiff is the United States, acting on behalf of the Drug Enforcement Administration (“DEA”).
2. Betances is a wholesale pharmaceutical distributor headquartered in Caguas, Puerto Rico. Betances is registered with DEA as a distributor of Schedule II-V controlled substances under provisions of the CSA.
3. Each DEA registrant is required to conduct its operations in accordance with the CSA and the regulations promulgated thereunder.
4. The CSA places a duty on registrants to maintain effective controls against diversion of controlled substances.

5. Under the CSA, distributors registered with DEA must operate a system to identify suspicious orders of controlled substances and inform DEA of suspicious orders. 21 U.S.C. § 832(a); 21 C.F.R. 1301.74(b).

6. Registered distributors must also report acquisitions and distributions of Schedule I and II controlled substances and certain Schedule III controlled substances to DEA's Automation of Reports and Consolidated Orders System ("ARCOS"). 21 U.S.C. § 827(d); 21 C.F.R. § 1304.33.

7. Registered distributors are also required to execute, fill, cancel, correct, file with DEA, and otherwise handle DEA "Form 222" order forms and their electronic equivalent for Schedules I and II controlled substances according to the provisions of 21 U.S.C. § 828 and Part 1305 of Title 21 of the Code of Federal Regulations.

8. In the Complaint, the United States alleges that Betances committed the following violations of the CSA from November 2016 to the date the Complaint was filed:

- a. Betances failed to maintain an adequate system to identify suspicious orders of controlled substances and failed to report suspicious orders of controlled substances to DEA, as required by 21 U.S.C. § 832(a) and 21 C.F.R. 1301.74(b). This includes failing to report to DEA at least 964 orders that the United States alleges were suspicious;
- b. Betances failed to accurately report to DEA its distribution of Schedule II controlled substances as required by 21 U.S.C. § 827(d) and 21 C.F.R. 1304.33. This includes failing to report to DEA at least 7.8 million dosage units of opioids that Betances distributed to pharmacies in Puerto Rico between May 2017 and July 2018; and

c. Betances failed to properly handle and document orders for controlled substances by:

- i. Filling hundreds of defective DEA Forms 222 containing alterations, erasures, or change in descriptions, in violation of 21 C.F.R. § 1305.15;
- ii. Filling at least 1,000 improperly voided or cancelled orders, in violation of 21 C.F.R. § 1305.19(b);
- iii. Failing to record supplier information on DEA Forms 222, in violation of 21 C.F.R. § 1305.13(b);
- iv. Failing to forward thousands of Copy #2 of DEA Forms 222 to DEA Caribbean Division Special Agent in Charge, at the close of the month during which the order was filled, in violation of 21 C.F.R. § 1305.13(d);
- v. Failing to maintain readily retrievable records of Scheduled III through V Controlled Substances, in violation of 21 C.F.R. § 1304.04(f) (2);
- vi. Distributing controlled substances to an entity using another registrant's DEA registration number; and
- vii. Distributing controlled substances using DEA Forms 222 signed by an unauthorized representative of a customer.

9. Betances specifically denies the allegations contained in paragraphs 8(a) and 8(b).

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, the parties enter into this Consent Decree without adjudication or admission of any issue of fact or law.

10. The conduct described in Paragraph 8 is referred to in this Consent Decree as the "Covered Conduct." The Covered Conduct is limited to conduct that occurred from November 1,

2016, to the date the Complaint in this case was filed. Nothing in this Consent Decree shall be construed to release Betances from any claim related to conduct that occurred after the date of the filing of the Complaint.

11. The United States contends that the Covered Conduct exposes Betances to civil penalties under 21 U.S.C. § 842(a)(5) and (c)(1). Additionally, the United States contends that Betances' failure to report to DEA orders that the United States alleges were suspicious exposes Betances to civil forfeiture pursuant to 21 U.S.C. § 881(a)(6).

12. The United States has conducted an analysis of Betances' financial condition based on Betances' sworn financial disclosures to the United States ("Financial Disclosures") and determined that the amount recoverable by the United States for the Covered Conduct substantially exceeds Betances' ability to pay.

13. On July 9, 2019, DEA conducted an administrative inspection on the premises of Betances in accordance with 21 U.S.C. §§ 822(f) and 880 and seized \$129,604.36 as part of the inspection ("Seized Items").

14. The Parties have reached a full and final mutually agreeable resolution of the United States' claims in this case and agree and stipulate to the Terms and Conditions set forth below.

TERMS AND CONDITIONS

NOW, THEREFORE, before the taking of any testimony, without the admission of any fact or law, in consideration of the mutual promises, covenants, and obligations set forth below, and for good and valuable consideration, the Parties agree, and IT IS HEREBY ORDERED as follows:

15. The Court's subject matter jurisdiction is undisputed and Betances consents to the Court's exercise of personal jurisdiction over it.

16. Venue is proper in this Court under 21 U.S.C. § 842(c)(1)(A), as well as 28 U.S.C. §§ 1391(b) and 1395(a). Betances consents to venue in this Court.

17. Betances agrees that the Complaint states a claim upon which relief may be granted.

18. DEA is the entity responsible for implementing and enforcing the CSA and may take administrative action against Betances to suspend or revoke Betances' DEA registration without seeking leave of this Court.

19. This Consent Decree has been negotiated by the Parties and the Court finds that the Consent Decree is fair, reasonable, and in the public interest.

20. This Consent Decree becomes effective the date that it is signed by the Court (the "Effective Date").

21. In consideration of the undertakings by Betances contained herein, and subject to the exceptions below (concerning excluded claims):

- a. Conditioned upon the United States' receipt of timely payments of the civil monetary penalties and forfeiture described below according to the schedule set forth below, DEA shall refrain from seeking the suspension or revocation of Betances' certificate of registration based on the Covered Conduct, and the United States shall refrain from filing any action for civil penalties under 21 U.S.C. § 842 based on, arising from, or related to the Covered Conduct.
- b. Upon the United States' receipt of Betances' full payment of the civil monetary penalties and forfeiture described below, the United States shall release Betances from all civil penalty claims under 21 U.S.C. § 842 and civil forfeiture under 21

U.S.C. §881(a)(6) that the United States has asserted, could have asserted, or may assert in the future against Betances related to the Covered Conduct.

22. In consideration of the undertakings of the United States contained herein, Betances fully and finally releases the United States, its agencies, officers, employees, servants, and agents from any claims (including attorney's fees, costs and expenses of every kind and however denominated) that Betances has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, employees, servants, and agents related to the investigation, prosecution, and settlement of the Covered Conduct.

Civil Monetary Penalties and Forfeiture

23. Betances shall pay to the United States the total sum of \$12,000,000 (twelve million dollars, the "Settlement Amount"), which includes a stipulated forfeiture amount of \$1,800,000 (one million eight hundred thousand dollars), in accordance with the payment schedule set forth below by electronic funds transfer pursuant to the written instructions provided to Betances by the United States Attorney's Office for the District of Puerto Rico.

24. Betances shall pay to the United States an initial payment of \$2,000,000 within 30 calendar days of the Effective Date of this Consent Decree. This initial payment shall be divided as follows: \$1,700,000 as part of the civil monetary penalties and \$300,000 as partial payment of the stipulated forfeiture amount.

25. Betances shall make subsequent payments as set forth below. Fifteen percent of each scheduled payment shall be paid via separate transfer and will go towards the forfeiture amount, until paid off in full.

- \$1,000,000 on or before July 31, 2024
- \$2,000,000 on or before July 31, 2025

- \$2,000,000 on or before July 31, 2026
- \$2,500,000 on or before July 31, 2027
- \$2,500,000 on or before July 31, 2028

26. Betances agrees to waive any formal civil forfeiture proceedings. Betances does not contest the stipulated forfeiture amount and agrees not to assert any claim or challenge to the stipulated forfeiture amount or assist any third party in asserting any claim or challenge to the stipulated forfeiture amount.

27. Betances also agrees to waive any claims for ownership over the Seized Items from the Administrative Inspection Warrant executed on July 9, 2019, under Civil Case No. 19-MJ-1363.

28. Betances warrants that the Financial Disclosures referenced in Paragraph 12 are complete and accurate. If the United States learns of any asset in which Betances had an interest of any kind that was not disclosed in the Financial Disclosures, or if the United States learns of any false statement or misrepresentation by Betances 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 \$1,200,000 or more, the United States may at its option: (a) reinstate its suit or file suit based on the Covered Conduct or (b) collect the full Settlement Amount in accordance with the Consent Decree plus one hundred percent (100%) of the net value of Betances' previously undisclosed assets. Betances agrees not to contest any collection action undertaken by the United States pursuant to this provision and agrees that it 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 reinstates its suit or files suit based on the Covered Conduct, Betances waives and agrees 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 Betances that claims will be reinstated or filed pursuant to this Paragraph and (b) relate to the Covered Conduct, except to the extent these defenses were available the date this Consent Decree was signed by the Court.

29. In exchange for valuable consideration provided in this Agreement, Betances acknowledges the following:

- a. Betances warrants that it has reviewed its financial situation and that it currently is solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I) and according to its current budget projections, will remain solvent following its 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 Betances, 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 Betances was 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 Betances' 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 Settlement Amount is paid in full, Betances 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 Betances' debts, or to adjudicate Betances as bankrupt or insolvent; or seeking appointment of a receiver, trustee, custodian, or other similar official for Betances or for all or any substantial part of Betances' assets, the United States may rescind the releases in this Agreement and bring any claim, action, or proceeding against Betances for the claims that would otherwise be covered by the releases provided in Paragraph 21 above.
- f. Betances agrees that any claim, action, or proceeding brought by the United States under Paragraph 29(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. Betances 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). Betances waives 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 claim, action, or proceeding brought by the United

States within 120 days of written notification to Betances that the releases have been rescinded pursuant to this paragraph, except to the extent such defenses were available on the date of this Consent Decree.

Compliance Terms

30. The terms below shall be defined as follows for purposes of the specific compliance requirements detailed in Paragraphs 31 through 38:

- a. "Controlled substance" is defined in 21 U.S.C. § 802(6). The term "threshold" means a limitation on the volume of a controlled substance or a particular category of controlled substances that Betances shall allow a customer to purchase in a particular period before triggering the investigation and approval process set forth in Paragraph 32 below.
- b. The term "highly diverted controlled substances" means the controlled substances that Betances designates as being subject to the most restrictive thresholds and/or supplemental due diligence because such substances have a higher risk of diversion compared to other controlled substances. Betances' list of highly diverted controlled substances currently includes, and shall continue to include, without limitation, the following: (i) oxycodone; (ii) hydrocodone; (iii) hydromorphone; (iv) methadone; (v) morphine; (vi) carisoprodol; (vii) alprazolam; (viii) tramadol; (ix) oxymorphone; (x) fentanyl; (xi) amphetamine; and (xii) buprenorphine. Betances shall add other controlled substances to the list of highly diverted controlled substances as needed based on information obtained from DEA and other sources related to drug diversion trends.

- c. The term "order" means a unique customer request on a specific date for a certain amount of a specific dosage form or strength of a controlled substance in one given instance, regardless of other requests made concurrently with that given request. For the purposes of this definition, each line item on an invoice or DEA Form 222 is a separate order.
- d. The term "dispensing activity data" means the following information regarding the controlled substances dispensed by a customer during a specific period: (a) the prescription number; (b) the patient's zip code; (c) the drug's name, strength, dosage form, and National Drug Code ("NDC") number; (d) the quantity of the drug dispensed and the days' supply; (e) the date the drug was dispensed; (f) the prescriber's name and DEA number; (g) the method of payment; and (h) the total number of prescriptions dispensed, broken down by controlled and non-controlled substances.

31. Betances shall maintain and implement a Controlled Substance Monitoring Program ("CSMP") designed to detect, prevent and maintain effective controls against diversion of controlled substances, and identify and report suspicious orders as required under the CSA and applicable implementing regulations.

32. Within 90 days of the Effective Date of this Consent Decree, Betances shall implement improved CSMP procedures and systems to review all orders of controlled substances and to detect and report suspicious orders to DEA to include the following:

- a. Betances shall review and enhance its methodology for calculating and establishing appropriate thresholds designed to detect potentially suspicious orders from customers. These thresholds shall be designed to identify orders of

unusual size, orders deviating substantially from a normal pattern, orders of unusual frequency, and otherwise suspicious orders. These thresholds shall be determined based not only on the customer's historical dispensing activity data, but also on the ordering patterns of comparable customers. When accounting for the volume of a controlled substance or category of controlled substances ordered by a customer, the threshold(s) shall do so on a per dose basis, not solely based on the volume of bottles ordered. Betances shall set more restrictive thresholds for orders of highly diverted controlled substances. Betances shall establish appropriate initial thresholds for new customers prior to supplying them with any controlled substances. Betances compliance personnel shall be exclusively responsible for establishing and modifying initial thresholds and may consult with other Betances personnel to gather information relevant to such determinations.

- b. Betances shall not fulfill any order that causes the customer to exceed its threshold(s), inclusive of orders that the customer places with backup distributors, without conducting a thorough and diligent investigation to determine whether the order is suspicious and must be reported to DEA. This investigation shall include, but not be limited to, contacting the customer to obtain an explanation for the increase in ordering and obtaining and reviewing a report from the customer reflecting its dispensing activity data for the preceding twelve (12) months. Betances' compliance personnel trained in detecting suspicious orders shall conduct this investigation and shall create documentation sufficiently specific to show the basis for their determination as to whether the order is

suspicious. All orders that Betances determines to be suspicious after such investigation shall be reported to DEA. Betances shall not respond to a suspicious order by shipping a reduced quantity of products without reporting the suspicious order to DEA. Any decision that an order is not suspicious and need not be reported to DEA must be approved in writing by Betances' Chief Compliance Officer, Director of Compliance, or Assistant Director of Compliance. In addition, Betances shall notify DEA Caribbean Division in writing of any decision that results in fulfilling an order that exceeds a customer's threshold(s).

- c. Betances shall review and enhance its procedures and systems for evaluating and approving customer requests for increased thresholds ("Threshold Change Requests"). Prior to approving a Threshold Change Request, Betances shall conduct a thorough and diligent investigation to determine whether the increased threshold is warranted. This investigation shall include, but not be limited to, contacting the customer to obtain the basis for the Threshold Change Request, obtaining and reviewing a report from the customer reflecting its most recent dispensing activity data, and conducting an on-site visit to the customer if the customer has not been subject to a site visit within the prior six months. Betances' compliance personnel shall conduct this investigation and shall create documentation sufficiently specific to show the basis for their determination as to whether the Threshold Change Request should be approved. Betances shall not temporarily increase thresholds to circumvent the requirement to conduct Threshold Change Request investigations. Any increase in a customer's threshold(s) must be approved in writing by Betances' Chief Compliance Officer,

Director of Compliance, or Assistant Director of Compliance. In addition, Betances shall notify DEA Caribbean Division in writing of any decision that results in the approval of a customer's Threshold Change Request.

- d. Betances shall review and enhance its procedures and systems for detecting patterns or trends in customer orders and dispensing activity that indicate a customer may be dispensing controlled substances for other than a legitimate medical purpose ("Red Flags"). In the event that Betances identifies a Red Flag associated with a customer, Betances shall conduct a thorough and diligent investigation, which includes review of dispensing activity data and the information provided by the customer in Betances' "Know Your Customer" form, to determine whether any orders or customer Red Flags should be reported to DEA. Red Flags include, but are not limited to:-

- i. A high percentage of the customer's controlled substance sales are paid for in cash.
- ii. The customer fills prescriptions for many patients who travel a far distance to obtain a prescription from a provider or from a pharmacy.
- iii. The customer frequently fills prescriptions for higher quantities than the accepted medical standards.
- iv. A high percentage of the customer's overall dispensing consists of controlled substances.
- v. A disproportionate percentage of the customer's controlled substance sales are for highly diverted controlled substances.
- vi. The customer fills prescriptions written by prescribers acting outside their

practice or specialty.

- vii. The customer fills prescriptions for prescribers who have been subject to discipline or a law enforcement action.
- viii. The customer dispenses the same quantity of highly diverted controlled substances to most patients.
- ix. Additional red flags identified by DEA or local pharmacy regulators.
- e. Upon identification of one or more Red Flags, Betances shall suspend and not resume distribution of controlled substances to the customer unless it reasonably concludes, based on specific and articulable facts, that there is a legitimate explanation for the identified Red Flag(s). Betances' compliance personnel trained in detecting suspicious orders shall conduct this investigation and shall create documentation sufficiently specific to show the basis for their determination, including its decision, if any, not to suspend distribution of controlled substances.
- f. Betances shall electronically submit all suspicious orders to DEA Headquarters via the Suspicious Orders Reporting System (SORS2). DEA agrees to provide Betances with instructions and procedures for electronically submitting suspicious orders. Betances shall submit and upload all suspicious orders to the SORS2 within two business days of its final conclusion that the order is suspicious. Betances shall not fulfill any order deemed to be suspicious.
- g. Betances shall improve its ARCOS reporting system to ensure proper and accurate reporting of all acquisitions and distributions of Schedule II, IIN and

IIIN Controlled Substances to ARCOS, through the ARCOS On-Line Reporting System.

33. Within 90 days of the Effective Date of this Consent Decree, Betances shall implement improved CSMP procedures and systems for conducting due diligence reviews of pharmacy customers to prevent the diversion of controlled substances.

- a. Betances shall review and enhance its customer onboarding procedures and systems to better assess whether prospective customers dispense controlled substances for only legitimate medical purposes. Betances shall, to the extent possible, verify any information that is self-reported by the prospective customer and relied upon to make this assessment. Prior to initiating the sale of controlled substances to a pharmacy, Betances' compliance personnel, or a qualified third party consultant acting on behalf of Betances, shall engage in at least the following due diligence: (i) conduct an on-site visit to the pharmacy and interview the pharmacist-in-charge; (ii) complete a report reflecting the findings based on this visit and interview and noting any areas of concern; (iii) review recent dispensing activity data for the pharmacy to identify any Red Flags; (iv) determine whether the pharmacy or the pharmacist-in-charge has been subject to any disciplinary action, and, if so, the basis for the disciplinary action; and (v) conduct a diligent inquiry to determine whether another distributor has previously suspended the pharmacy's ability to purchase controlled substances, and, if so, the reason. In the event that Betances identifies a Red Flag that does not have a legitimate explanation or Betances' due diligence reveals any other credible information suggesting that the pharmacy may be engaging in diversion, Betances

shall not sell controlled substances to the pharmacy and shall report its findings and the results of its due diligence review to DEA Caribbean Division within two business days of the conclusion of its due diligence review.

- b. Betances shall review and enhance its procedures and systems for conducting meaningful due diligence of existing customers that purchase controlled substances to better assess whether existing customers dispense controlled substances for only legitimate medical purposes. Betances' compliance personnel, or a qualified third party consultant acting on behalf of Betances, must engage in at least the following due diligence for each controlled substance customer: (i) conduct on-site visits and interviews of the pharmacist-in-charge, which shall be done at least once a year for Betances' 20 largest customers of highly diverted controlled substances, as measured by total volume of sales of highly diverted controlled substances during the prior year, and at least once every three years for all other controlled substances customers; (ii) complete a report reflecting their findings based on the visit and interview and noting any areas of concern; (iii) at least three times each calendar year for Betances' 20 largest customers of highly diverted controlled substances, as measured by total volume of sales of highly diverted controlled substances during the prior year, and at least once each calendar year for the 100 largest customers of all controlled substances, obtain and review the pharmacy's dispensing activity data for the prior three months to identify any Red Flags; (iv) obtain updated completed questionnaires from the pharmacy on an annual basis; and (v) conduct all necessary additional due diligence in response to any information or events

raising concerns of potential diversion activities (*e.g.*, the receipt of reliable information from law enforcement about possible diversion, the receipt of information regarding the suspension or revocation of a DEA registration or state license). In the event that Betances identifies a Red Flag that does not have a legitimate explanation or Betances' due diligence reveals any other credible information suggesting that the pharmacy may be engaging in diversion, Betances shall not sell controlled substances to the pharmacy and shall report its findings and the results of its due diligence review to DEA Caribbean Division within two business days of the conclusion of the due diligence review. In addition, upon identification of such evidence suggesting diversion, including the presence of one or more Red Flags, Betances shall suspend and not resume distribution of controlled substances to the customer unless it reasonably concludes, based on specific and articulable facts, that no such diversion is occurring, including that there is a legitimate explanation for the evidence suggesting diversion and the identified Red Flag(s). Betances compliance personnel trained in detecting suspicious orders shall conduct this investigation and shall create documentation sufficiently specific to show the basis for their determination, including its decision, if any, not to suspend distribution of controlled substances.

- c. All steps taken with respect to the due diligence review of prospective or existing customers shall be documented in the customer's file.

34. Betances shall ensure that all policies and procedures relating to its CSMP are included in an updated version of its compliance manual ("CSMP Manual").

35. For a period of five years after the Effective Date of this Consent Decree, Betances shall submit periodic reports to DEA Caribbean Division and the U.S. Department of Justice, Consumer Protection Branch ("CPB"). Betances shall submit its first report within 90 calendar days of the Effective Date of this Consent Decree. After making its first report, Betances shall thereafter make a report every 360 calendar days (a "Reporting Period"). The reports shall be submitted within thirty days after the last day of the Reporting Period. Each report shall include the following:

- a. A list of all Betances compliance personnel, as well as any third-party consultants used by Betances to perform compliance functions;
- b. Betances' list of highly diverted controlled substances as of the end of the Reporting Period;
- c. A list of Betances' 20 largest customers of highly diverted controlled substances, as measured by total volume of sales of highly diverted controlled substances during the Reporting Period, and a breakdown of the sales of highly diverted controlled substances to each of these customers during the Reporting Period;
- d. A description of the methodologies used during the Reporting Period to calculate and establish thresholds for new and existing Betances customers, as well as any changes that were made to the methodologies since the prior Reporting Period.
- e. The total number of suspicious orders reported to DEA during the Reporting Period; and
- f. A copy of any version of the CSMP Manual that was in effect during the Reporting Period, which shall include, among other things, a description of the manner in which Betances identified and reported suspicious orders to DEA

during the Reporting Period and a description of the procedures and systems in place during the Reporting Period to conduct due diligence reviews of new and existing pharmacy customers.

36. For a period of five years after the Effective Date of this Consent Decree, Betances shall voluntarily submit to DEA inspections pursuant to 21 C.F.R. § 1316.03 and 21 C.F.R. § 1316.08, at any time, without condition or advance notice, allowing DEA to inspect Controlled Substances records, files, inventories, and any other records required to be maintained and kept by a distributor, in order to verify compliance with this Consent Decree and with the CSA, without requiring an Administrative Inspection Warrant, Search Warrant, court order, or other means of entry.

37. Betances shall maintain customer due diligence files and all other records sufficient to document compliance with this Consent Decree during the period from the Effective Date through six months after the last Reporting Period.

38. Betances may notify DEA Caribbean Division of any compliance term set forth in this Consent Decree that it believes is unduly burdensome, inconsistent with applicable law or regulation, excessively expensive, or otherwise inadvisable, as well as the basis for such conclusion. Such notification shall be sent to DEA Caribbean Division and CPB and must include a written proposal of an alternative approach, policy, procedure or system that Betances believes will achieve the same objective or purpose as the challenged provision. DEA shall in its sole discretion, determine whether to accept Betances' proposed revision, to maintain the existing provision, or to adopt a different alternative.

Material Breach and Default Provisions

39. Betances and the United States agree that if Betances fails to comply with the material obligations set forth in this Consent Decree as described in Paragraph 41, below, DEA may impose a registration modification and suspend Betances' Schedule-II, DEA Registration for a period not to exceed nine (9) months. This provision does not in any way supplant or waive any other remedy available to DEA under the CSA and implementing regulations or civil penalties available to the United States under 21 U.S.C. § 842 (c) for future misconduct.

40. DEA, in its sole discretion, may elect to reduce or waive any modification and/or penalty should a violation or deficiency occur and is timely reported to DEA. If DEA elects to exercise its discretion and reduce or waive any modification or penalty, DEA shall notify Betances in writing. The decision by DEA to waive enforcement of any such provision does not constitute a waiver as to any other remedy it may have under the CSA or implementing regulations.

41. The following obligations under this Consent Decree, if violated, are considered "Material Violations" subject to the imposition of registration modification for a period not to exceed nine (9) months:

- a. Other than the Covered Conduct or any violations that DEA has waived or Betances has cured, Betances' failure to submit any Suspicious Order Report as required in Paragraph 32 (a) through (g).
- b. Other than the Covered Conduct or any violations that DEA has waived or Betances has cured, Betances' failure to report to ARCOS, through the ARCOS On-Line Reporting System, all reportable acquisitions and distributions of Schedule II, IIN and IIIN Controlled Substances, as required in Paragraph 32 (f) and 21 C.F.R. § 1304.33.

c. DEA reserves the right to impose registration modification for any unaddressed or recurring computer errors, other than the Covered Conduct, that prevent the submission and timely notifications or reports as required in Paragraph 41 (a) and (b), or as required under this Consent Decree.

42. Upon a finding made by DEA, during the term of this Consent Decree, that Betances committed a Material Violation, DEA Caribbean's Office of Diversion Control, must promptly notify Betances of their finding identifying the Material Violation and DEA's intention of imposing the registration modification.

43. Betances shall have ten (10) calendar days after receipt of notice of DEA's intention to impose a registration modification pursuant to the Consent Decree to respond in writing that they have cured the Material Violation.

44. DEA, after receipt and review of Betances' response to the Material Violation, in its sole discretion, may deem the matter cured or impose the registration modification.

Additional Terms

45. Nothing in this Consent Decree shall prevent DEA from seeking the suspension or revocation of Betances' DEA registration, or any other administrative remedy, for conduct or actions in violation of the CSA, other than the Covered Conduct, without seeking leave of this Court.

46. Nothing in this Consent Decree shall prevent, preclude, limit, or prejudice the right of the United States to enforce the CSA by commencing a civil action against Betances for violations of the CSA or regulations promulgated thereunder for conduct other than the Covered Conduct.

47. Nothing in this Consent Decree shall prohibit or limit any other component within the U.S. Department of Justice or any other law enforcement, administrative, or regulatory agency of the United States from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct. DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any agency that has initiated or initiates an investigation, action, or proceeding involving the Covered Conduct, but will not otherwise initiate or refer any action to any U.S. Attorney's Office or any component of the U.S. Department of Justice, based on the Covered Conduct.

48. Notwithstanding any term of this Consent Decree, the United States specifically reserves and does not release:

- a. Any criminal liability;
- b. Any claim arising under Title 26, United States Code (Internal Revenue Code);
- c. Except as explicitly stated in this Consent Decree, any administrative liability, including the suspension and debarment rights of any federal agency;
- d. Any liability based on breach of the obligations created by this Consent Decree; and
- e. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct.

49. All notifications, correspondence, and communications to the DEA Caribbean Division required by the terms of this Consent Decree shall be prominently marked "Decree Correspondence" and delivered by electronic mail and/or hard copy to DEA Group Supervisor Carlos A. Nazario, Metro Office Park, Millennium Park Plaza, 15 Calle 2 Suite 710 Guaynabo,

PR 00968-1743, email: carlos.a.nazario@dea.gov. Unless otherwise directed by CPB in writing, any notice to CPB under this Consent Decree shall be given by electronic mail to Consumer.Compliance@usdoj.gov and to any additional email addresses provided by CPB. The subject line of the email must begin with "Betances." In the event that electronic mail is unavailable, the notice may be sent by personal delivery, overnight delivery by a recognized delivery service, or registered or certified mail to an address provided by CPB. Notice shall be effective upon actual receipt by CPB. Notice to the United States Attorney's Office for the District of Puerto Rico under this Consent Decree shall be given by both electronic mail to david.o.martorani@usdoj.gov and personal delivery, overnight delivery by a recognized delivery service, or registered or certified mail to Torre Chardon, Suite 1201, 350 Carlos Chardon Street, San Juan, Puerto Rico 00918.

50. Nothing in this Consent Decree 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.

51. The Parties warrant that, in evaluating whether to execute this Consent Decree, they (a) intended that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to Betances within the meaning of 11 U.S.C. § 547(c)(1); and (b) concluded that the mutual promises, covenants, and obligations set forth herein do, in fact, constitute such a contemporaneous exchange. In addition, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value which is not meant to hinder or delay payment to, or to defraud any entity to which Betances was or became indebted on or after the date of this transfer, all within the meaning of 11 U.S.C. § 548(a)(1).

52. This Consent Decree binds and is intended to benefit only the Parties. This Consent Decree is not intended to be, and shall not be interpreted to constitute, a release of any person or entity not identified or referred to herein.

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

54. Each Party represents that it freely and voluntarily enters into this Consent Decree without any degree of duress or compulsion. Betances also acknowledges it was represented by legal counsel of its choosing throughout the negotiation and execution of this Consent Decree.

55. This Court retains jurisdiction over any dispute arising between the Parties related to this Consent Decree. However, as provided in Paragraph 45, DEA may seek the suspension or revocation of Betances' DEA registration, or any other administrative remedy, for conduct or actions in violation of the CSA, other than the Covered Conduct, without seeking leave of this Court.

56. The undersigned individuals represent and warrant that they are fully authorized to execute this Consent Decree on behalf of the Parties listed below.

57. This Consent Decree is binding on Betances and its successors, transferees, heirs, and assigns.

SO ORDERED this 3rd day of November 2023.



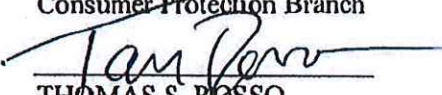
United States District Judge
District of Puerto Rico

For Plaintiff, the United States of America:

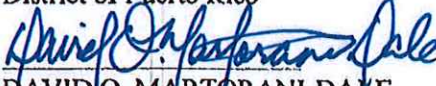
BRIAN M. BOYNTON
Principal Deputy Assistant Attorney
General, Civil Division

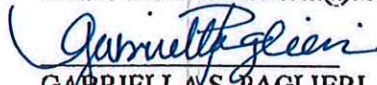
ARUN G. RAO
Deputy Assistant Attorney General
Civil Division

AMANDA N. LISKAMM
Director
Consumer Protection Branch

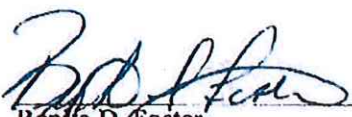

THOMAS S. ROSSO
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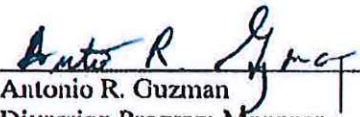
W. STEPHEN MULDROW,
United States Attorney for the
District of Puerto Rico


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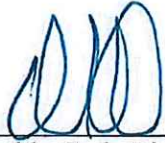

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For the Drug Enforcement Administration:

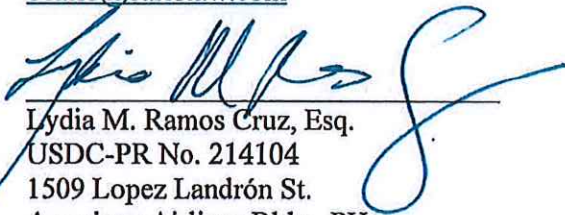

Renita D. Foster
Special Agent in Charge
Drug Enforcement Administration
Caribbean Division


Antonio R. Guzman
Diversion Program Manager
Drug Enforcement Administration
Caribbean Division

For Defendant, Drogueria Betances LLC:



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