IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA

UNITED STATES OF AMERICA, Plaintiff, v. STRATUS PHARMACEUTICALS, INC., and SONAR PRODUCTS, INC., corporations, and ALBERTO HOYO, and JUAN CARLOS BILLOCH individuals, Defendants.	Civil Action No. 17-cv-21659

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by and through its undersigned attorneys, having filed a Complaint for Permanent Injunction against Stratus Pharmaceuticals, Inc. and Sonar Products, Inc., corporations, and Alberto Hoyo and Juan Carlos Billoch, individuals (hereinafter, collectively, "Defendants"), and Defendants having appeared and consented to entry of this Decree without contest, and before any testimony has been taken, and the United States of America, having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter of this action under 21 U.S.C. § 332 and has personal jurisdiction over all parties to this action under 28 U.S.C. §§ 1331, 1337, and 1345. Venue is proper in this district under 28 U.S.C. § 1391(b) and (c).

2. The Complaint states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* (the "Act").

3. The Complaint alleges that Defendants violate 21 U.S.C. § 331(d) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce new drugs within the meaning of 21 U.S.C. § 321(p) that are neither approved under 21 U.S.C. § 355(b) or (j), nor exempt from approval under 21 U.S.C. § 355(i).

4. The Complaint alleges that Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of drug that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), in that the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice ("cGMP") set forth in 21 C.F.R. Part 211.

5. The Complaint alleges that Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of drug that are misbranded within the meaning of 21 U.S.C. § 352(f)(1).

6. The Complaint alleges that Defendants violate 21 U.S.C. § 331(k) by causing articles of drug that they hold for sale after shipment of one or more of their component parts in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B).

7. The Complaint alleges that Defendants Sonar Products, Inc., Alberto Hoyo, and Juan Carlos Billoch violate 21 U.S.C. § 331(k) by causing articles of drug held for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1).

8. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and all persons in active concert

or participation with any of them (including individuals, directors, partnerships, corporations, subsidiaries, franchisees, affiliates, and "doing business as" entities), who receive notice of this Decree by personal service or otherwise (collectively, "Associated Person(s)"), are permanently restrained and enjoined under 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, from directly or indirectly manufacturing, processing, packing, labeling, holding, selling, and distributing any articles of drug from 12379 SW 130th Street, Miami, Florida, or 609 Industrial Road, Carlstadt, New Jersey, or at or from any other facility where Defendants now or in the future directly or indirectly manufacture, process, pack, label, hold, sell, or distribute any articles of drug ("Defendants' Facilities"), unless and until:

A. Defendants' and Associated Persons' methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute drugs are established, operated, and administered in conformity with cGMP. 21 U.S.C. § 351(a)(2)(B) and 21 C.F.R. Parts 210 and 211;

B. Defendants establish and document management control over Quality Assurance ("QA") and Quality Control ("QC") for Defendants' Facilities to ensure continuous compliance with the Act, its implementing regulations, and this Decree. Responsibility for management control over QA and QC shall be vested in an individual who shall be authorized and responsible for all QA and QC functions at all of Defendants' Facilities, including ensuring the establishment, implementation, and maintenance of a comprehensive written QA and QC program ("QA/QC Program") as described in paragraph 8(E)(ii), to ensure that all drug products manufactured, processed, packed, held, and distributed by Defendants at or to all of Defendants' Facilities have the safety,

identity, strength, quality, purity, and potency that they purport or are represented to possess, and are in compliance with the provisions of this Decree;

C. Defendants select and retain, at their expense, an independent person or persons (the "Expert"), to conduct inspections of Defendants' operations and to review Defendants' procedures and methods for manufacturing, processing, packing, labeling, holding, selling, and distributing articles of drug, to determine whether their methods, facilities, and controls are operated and administered in conformity with this Decree, the Act, and its implementing regulations. The Expert shall be qualified by education, training, and experience to conduct such inspections, have specific expertise in evaluating compliance with the cGMP requirements for drugs as set forth in 21 C.F.R. Part 211, have expertise in microbiology as it relates to non-sterile human drug manufacturing, and be without personal or financial ties (other than a consulting agreement between the parties) to Defendants' officers or employees or their families;

D. Defendants shall notify the United States Food and Drug Administration ("FDA") in writing of the identity and qualifications of the Expert within ten (10) business days of retaining such Expert;

E. The Expert shall perform a comprehensive inspection of Defendants' Facilities and the methods and controls used to manufacture, process, package, label, hold, and distribute drugs. The Expert shall determine whether Defendants' Facilities and the methods and controls used to manufacture, process, package, label, hold, and distribute drugs are in compliance with cGMP for drugs, the Act and its implementing regulations, and this Decree. The Expert's report of the inspection shall be submitted to FDA and shall include, but not be limited to, the following:

i. An evaluation of Defendants' current state of compliance with respect to the deviations set forth on FDA's Lists of Inspectional Observations issued to Defendants since January 1, 2014; and

ii. An evaluation of whether Defendants have established and implemented a comprehensive quality system with reliable manufacturing operations and a written QA/QC Program that is adequate to ensure continuous compliance with the Act, its implementing regulations, and this Decree. Responsibility for management control over QA and QC shall be vested in an individual whose responsibilities are separate from Defendants' manufacturing, processing, packaging, labeling, holding, and distributing operations, and shall be authorized and responsible for all QA and QC functions at all of Defendants' Facilities, including ensuring the establishment, implementation, and maintenance of a comprehensive written QA/QC Program to ensure that all drug products manufactured, processed, packed, held, and distributed by Defendants at all of Defendants' Facilities have the safety, identity, strength, quality, purity, and potency that they purport or are represented to possess, and are in compliance with the provisions of this Decree. The QA/QC Program shall include resources, systems, and procedures to ensure that:

(1) Defendants follow written production and process control procedures in the execution of production and process control functions and record and justify any deviation from the procedures;

(2) Defendants' manufacturing operations are conducted using suitably designed equipment, facilities, and processes with demonstrated

capability to assure reliable manufacturing performance and consistent drug quality;

(3) Defendants, in a timely manner, thoroughly investigate (a) product deviations; (b) reports of complaints regarding Defendants' products; and (c) any unexplained discrepancy or the failure of a batch of drug or any of its components to meet any product or component specifications, including the extension of such investigation to other batches of the same drug and other drugs that may have been associated with the specific failure or discrepancy; and take required and timely corrective actions for all products and components that fail to meet their specifications; and

(4) Defendants establish systems to ensure that their written standard operating procedures ("SOPs") addressing all facets of cGMP are controlled and periodically re-evaluated by the QA/QC Program personnel so that they remain in continuous compliance with cGMP. Such established systems must require that (a) Defendants' QA/QC Program personnel are promptly notified in writing of all deviations and/or problems that could affect the safety, identity, strength, quality, and purity of any drug; (b) Defendants' QA/QC Program personnel participate in or monitor the implementation and verification of corrective actions to prevent future occurrences of such deviations and/or problems; and (c) there are systems to ensure that such written SOPs are continuously followed, including written SOPs that specify the responsibilities and

procedures applicable to QA/QC Program personnel, and establish systems to ensure such SOPs are followed;

F. The Expert shall perform documented release certifications for each production batch record for the first ten (10) batches of each drug product manufactured after Defendants resume manufacturing operations pursuant to the written notification set forth in paragraph 8(J) before such lot may be distributed into interstate commerce. The Expert may choose to submit a separate certification report for issues specific to the drug products distributed by the Defendants prior to submitting a separate certification report for drug products manufactured for third-parties, so long as no more than two (2) reports are submitted to FDA pursuant to this subparagraph. The Expert's report shall contain, but not be limited to, the following:

i. A determination of whether Defendants have established and implemented adequate procedures, processes, equipment, and facilities designed to prevent microbiological contamination of each component and batch of drug product required to be free of objectionable organisms including evaluating the efficacy and suitability of any preservatives;

ii. A determination of whether Defendants have qualified their water system and developed and implemented appropriate specifications and test plans to ensure that such water is of the quality needed to manufacture their drug products;

iii. A determination of whether the accuracy, sensitivity, specificity, and reproducibility for all test methods used by Defendants have been established and documented;

iv. A determination of whether Defendants have established and are following laboratory controls that include scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality and purity;

v. A determination of whether Defendants have established and are following written procedures for cleaning and maintenance of equipment, including utensils, used in the manufacturing, processing, packing, labeling, holding, selling, and distributing of drug products;

vi. An evaluation of whether Defendants' Quality Assurance Unit reviews and approves all drug product production and control records to determine compliance with all established, written procedures before a batch is released or distributed, as required by 21 C.F.R.§ 211.192;

vii. A determination of whether Defendants have processes in place to ensure that when one or more drug manufacturing, processing, packing, labeling, holding, selling, and distributing functions are contracted or outsourced to another party, responsibilities are defined for each party involved, periodic audits are performed, the contracted or outsourced site is appropriately monitored, and appropriate product and process information is promptly transferred from the Defendants to the other party;

viii. A determination of whether Defendants have corrected all violations set forth in FDA's Inspectional Observations ("Forms FDA 483") from all prior FDA inspections;

ix. A determination of whether, based upon this comprehensive inspection, Defendants' operations are operated in conformity with this Decree, the Act, and its implementing regulations. The Expert shall submit his/her report(s) to FDA at the addresses specified in paragraph 22; and

x. A written report to FDA with the actions that Defendants have taken to (a) correct all violations brought to Defendants' attention by the Expert and/or set forth in FDA's Forms FDA 483 from all prior FDA inspections since January 1, 2014; and (b) ensure that the methods used in, and the facilities and controls used for manufacturing, processing, packing, labeling, holding, selling, and distributing articles of drug are designed, operated, and administered, and will be continuously operated and administered, in conformity with this Decree, the Act, and its implementing regulations. Defendants shall include with their report a copy of a written certification from the Expert that Defendants are in compliance with this Decree, the Act, and its implementing regulations;

G. Within twenty (20) business days after entry of this Decree, Defendants shall give written notice to FDA that, at their own expense and under FDA's supervision, they are prepared to destroy all articles of drug in their possession. Defendants' notice shall specify the proposed time, place, and method of destruction ("Destruction Plan"). Defendants shall neither commence nor permit any other person to commence destruction until they have received written authorization from FDA to commence the destruction;

H. FDA inspects Defendants' operations within sixty (60) calendar days of receiving the Expert's report, or as soon as practicable in the event that FDA representatives are attending to public health matters or exigencies, to determine whether the requirements of this Decree have been met, and whether Defendants' operations are otherwise operated in conformity with cGMP, the Act, and its implementing regulations;

I. Defendants pay all costs of expenses incurred under paragraph 8 for FDA inspections, investigations, supervision, reviews, examinations, evaluations, and analyses, at the rates set forth in paragraph 18 of this Decree; and

J. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in paragraph 8. In no circumstance shall FDA's silence be construed as a substitute for written notification.

9. The requirements of subparagraphs 8(A)-(G) of this Decree are applicable to Defendants' Facility located at 12379 SW 130th Street, Miami, Florida; however, nothing in paragraph 8 of this Decree shall require Defendants to destroy, or preclude Defendants from receiving, holding, selling, or distributing, articles of drug from Defendants' Facility located at 12379 SW 130th Street, Miami, Florida immediately upon entry of this Decree, provided that such articles of drug comply with the Act, its implementing regulations, and this Decree. Nothing in this paragraph exempts Defendants' Facility located at 12379 SW 130th Street, Miami, Florida, from other paragraphs of this Decree.

10. For the purposes of subparagraphs 8(A)-(G), paragraph 14, and paragraph 17 of this Decree, Defendants' Facilities do not include the facility located at 16311 NW 52nd Ave., Miami Gardens, Florida, 33014.

11. Upon entry of this Decree, Defendants and each and all of its Associated Person(s) who receive notice of this Decree by personal service or otherwise are permanently restrained and enjoined, pursuant to 21 U.S.C. § 332(a), from directly or indirectly manufacturing, processing, packing, labeling, holding, selling, and distributing any new drugs within the meaning of 21 U.S.C. § 321(p), including, but not limited to, Lidocaine 3% - Hydrocortisone 0.5% Cream Kit, Claris Clarifying Wash, Sodium Sulfacetamide 10% and Sulfur 2% Cleanser, Sodium Sulfacetamide 9% and Sulfur 4.5%, X-Viate 40% Gel, and X-Viate 40% Lotion, or any products labeled similarly to such products and containing active ingredient(s), unless and until an approved new drug application, an abbreviated new drug application, or an investigational new drug application filed pursuant to 21 U.S.C. §§ 355(b), (j), or (i) respectively, held by Defendants, is in effect for the article of drug, or unless the product strictly conforms with all of the requirements set forth in an applicable FDA over-the-counter ("OTC") monograph, 21 C.F.R. Part 330, and complies with all applicable labeling requirements, including 21 C.F.R. Part 201. Nothing in this paragraph or paragraph 11 or paragraph 12 shall preclude Defendants from marketing a drug subject to an ongoing Drug Efficacy Study Implementation ("DESI") proceeding during the pendency of that proceeding. The preceding sentence does not apply when a DESI proceeding closes. No provision of this Decree shall affect the authority of the United States of America to bring an action against Defendants for a violation of the Act and/or its implementing regulations.

12. Upon entry of this Decree, Defendants and each and all of their Associated Person(s) who receive notice of this Decree by personal service or otherwise are permanently restrained and enjoined, pursuant to 21 U.S.C. § 332(a), from directly or indirectly doing or causing to be done any act that:

A. Violates the Act, 21 U.S.C. § 331(d), and results in the introduction or delivery for introduction into interstate commerce of new drugs, as defined by 21 U.S.C. § 321(p), that are neither approved under 21 U.S.C. § 355, nor exempt from approval;

B. Violates the Act, 21 U.S.C. § 331(a), and results in the introduction or delivery for introduction into interstate commerce of articles of drug that are adulterated and/or misbranded; or

C. Violates the Act, 21 U.S.C. § 331(k), and results in an article of drug becoming adulterated while held for sale after shipment of one or more of its components in interstate commerce.

13. Upon entry of this Decree, Defendants Sonar Products, Inc., Alberto Hoyo, and Juan Carlos Billoch, and each and all of their Associated Person(s) who receive notice of this Decree by personal service or otherwise, are permanently restrained and enjoined, pursuant to 21 U.S.C. § 332(a), from directly or indirectly doing or causing to be done any act that violates the Act, 21 U.S.C. § 331(k), and results in an article of drug becoming misbranded while held for sale after shipment of one or more of its components in interstate commerce.

14. After Defendants have complied with paragraphs 8(A)–(I) and FDA has notified Defendants in writing pursuant to paragraph 8(J), Defendants shall retain an independent person or persons (the "Auditor"), at Defendants' expense, to conduct audit inspections of Defendants' drug manufacturing operations at Defendants' Facilities, not less than once every six (6) months for a period of one (1) year and not less than once every twelve (12) months for a period of four (4) years thereafter, for a total of five (5) years. The Auditor shall be qualified by education, training, and experience to conduct such inspections, and shall be without personal or financial ties (other than a consulting agreement entered into by the parties) to Defendants' officers or

employees or their families. The Auditor may be the same person or persons described as the Expert in paragraph 8(C). Additionally:

A. At the conclusion of each audit inspection, the Auditor shall prepare a written audit report (the "Audit Report") analyzing whether Defendants' operations are operated and administered in compliance with cGMP, the Act, its implementing regulations, and this Decree, and identifying in detail any deviations from the foregoing ("Audit Report Observations"). As part of every Audit Report, except the first, the Auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous Audit Report Observations. The Audit Reports shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than twenty (20) business days after the date the audit inspections are completed. If any Audit Report identifies any deviations from the Act, its implementing regulations, and/or this Decree, FDA may, in its discretion, require that the five (5) year auditing cycle be extended or begin anew. In addition, Defendants shall maintain complete Audit Reports and all of their underlying data in separate files at Defendants' Facilities and shall promptly make the Audit Reports and underlying data available to FDA upon request; and

B. If an Audit Report contains any adverse Audit Report Observations, Defendants shall, within thirty (30) business days of receipt of the Audit Report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the Audit Report, Defendants believe that correction of any adverse Audit Report Observation will take longer than thirty (30) business days, Defendants shall, within ten (10) business days of receipt of the Audit Report, propose a schedule for

completing corrections ("Correction Schedule"), and provide justification for the additional time. Defendants shall complete their corrections within thirty (30) business days, unless FDA approves in writing the Correction Schedule, in which case Defendants shall complete all corrections according to the approved Correction Schedule. In no circumstance shall FDA's silence be construed as a substitute for written approval. Within thirty (30) business days of Defendants' receipt of an Audit Report, or within the time period provided in a Correction Schedule approved by FDA, the Auditor shall review the actions taken by Defendants to correct the adverse Audit Report Observation(s). Within five (5) business days of the beginning of that review, the Auditor shall report in writing to FDA whether each of the adverse Audit Report Observations has been corrected and, if not, which adverse Audit Report Observations remain uncorrected.

15. Upon entry of this Decree, if at any time FDA determines, based on the results of an inspection, the analysis of a sample, a report, a review, or any other information, that Defendants have failed to comply with any provision of this Decree, have violated the Act or its implementing regulations, and/or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, and/or its implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate corrective action, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease manufacturing, processing, packing, labeling, holding, selling, and/or distributing any or all articles of drugs;

B. Recall, at Defendants' sole expense, any articles of drug that are unapproved,

adulterated, misbranded, or otherwise in violation of this Decree, the Act, or its implementing regulations;

C. Revise, modify, expand, or continue to submit any reports or plans prepared pursuant to this Decree;

D. Submit additional notifications, reports, or any other materials or information to FDA;

E. Issue a safety alert;

F. Issue a press release about a safety issue or recall; and

G. Take any other corrective actions as FDA, in its discretion, deems necessary to bring Defendants into compliance with this Decree, the Act, and its implementing regulations.

The provisions of paragraph 15 shall be apart from, and in addition to, all other remedies available to FDA.

16. Upon receipt of any order issued by FDA pursuant to paragraph 15, Defendants shall immediately and fully comply with the terms of the order. Any cessation of operations or other action described in paragraph 15 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations, and that Defendant may, therefore, resume operations.

17. FDA shall be permitted, without prior notice and as FDA deems necessary, to make inspections of Defendants' Facilities and take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the Act, and its implementing regulations. During inspections of Defendants' Facilities, FDA shall be permitted to have immediate access to buildings, equipment, raw ingredients, in-process materials, finished

products, containers, packing material, labeling, and other material therein; take photographs and make video recordings; take samples of raw ingredients, in-process materials, finished products, containers, packing material, labeling, and other material; to take photographs and make video recordings; to take samples of Defendants' finished and unfinished materials and products, containers, labeling, and other promotional material; and examine and copy all records relating to the manufacture, processing, packing, labeling, holding, selling, and distribution of any and all articles of drug and their respective components. The inspection shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to conduct inspections under the Act, 21 U.S.C. § 374.

18. Defendants shall reimburse FDA for the costs of all inspections, investigations, supervision, reviews, examinations, evaluations, and analyses that FDA deems necessary to evaluate Defendants' compliance with this Decree. The costs shall be borne by Defendants at the prevailing rates in effect at the time the costs are incurred. As of the date this Decree is signed by the parties, the rates are $93.26 per hour or fraction thereof per representative for inspection work; $111.77 per hour or fraction thereof per representative for analytical work; and $0.535 per mile for travel expenses for travel by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per representative and per day for subsistence expenses, where necessary. In the event that the standard rates generally applicable to FDA's supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of this Court.

19. Within ten (10) business days after entry of this Decree, Defendants shall post a copy of

this Decree in common areas at Defendants' Facilities and at any other location at which the Defendants conduct business, including those at which it contracts to manufacture, store, or distribute drugs, and shall ensure that the Decree remains posted for as long as it remains in effect. Within twenty (20) business days after entry of this Decree, Defendants shall provide to FDA an affidavit stating the fact and manner of its compliance with this paragraph.

20. Within ten (10) business days after entry of this Decree, Defendants shall provide a copy of the Decree by personal service or certified mail (restricted delivery, return receipt requested) to each Associated Person(s). Within twenty (20) business days after entry of this Decree, Defendants shall provide to FDA an affidavit stating the fact and manner of its compliance with this paragraph, and identifying the names, addresses, and positions of all persons who have received a copy of this Decree.

21. In the event that Defendants become associated with any additional Associated Person(s) at any time after entry of this Decree, Defendants shall immediately provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to such Associated Person(s). Each time a Defendant becomes associated with an additional Associated Person(s), it shall, within ten (10) business days of commencement of the association, provide to FDA an affidavit stating the fact and manner of its compliance with this paragraph, and identifying the names, addresses, and positions of all persons who have received a copy of this Decree pursuant to this paragraph. Within ten (10) business days of receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate compliance with this paragraph, Defendants shall provide such information or documentation to FDA.

22. Defendants shall notify FDA in writing at least ten (10) business days before any change in ownership, name, or character of its business that occurs after entry of this Decree, including

an incorporation, reorganization, creation of a subsidiary, relocation, dissolution, bankruptcy, assignment, sale, or any other change in the structure or identity of Stratus Pharmaceuticals, Inc. or Sonar Products, Inc., or the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect obligations arising out of this Decree. Defendants shall provide a copy of this Decree to any potential successor or assignee at least twenty (20) business days prior to any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) business days prior to such assignment or change in ownership.

23. All decisions specified in this Decree shall be vested in the discretion of FDA and shall be final. When contested by Defendants, FDA's decisions under this Decree shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

24. All notifications, correspondence, and communications required to be sent to FDA by the terms of this Decree shall be addressed to both the District Director, FDA Florida District Office, 555 Winderley Place, Suite 200, Maitland, FL 32751, and the District Director, FDA New Jersey District Office, 10 Waterview Boulevard, 3rd Floor, Parsippany, New Jersey 07054, and shall reference the case name and civil action number.

25. The parties may, at any time, petition each other in writing to extend any deadline provided herein, and the parties may grant such an extension without seeking leave of the Court. Any such petitions shall not become effective unless and until granted in writing.

26. Should Defendants fail to comply with any provision of this Decree, the Act, or its implementing regulations, it shall pay to the United States of America the sum of Ten Thousand

Dollars ($10,000.00) in liquidated damages for each day such violation continues; an additional sum of Ten Thousand Dollars ($10,000.00) in liquidated damages for each violation of this Decree, the Act, or its implementing regulations; and an additional sum equal to five (5) times the retail value of each shipment of an unapproved new drug, an adulterated drug, and/or a misbranded drug in liquidated damages for each such unlawful shipment. Defendants understand and agree that the liquidated damages specified in this paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States of America to seek, and the Court to impose, additional criminal or civil penalties based on conduct that may also be the basis for payment of the liquidated damages.

27. Should Plaintiff bring, and prevail in, a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, reimburse Plaintiff for its attorneys' fees and overhead, investigational and analytical expenses, expert witness fees, travel expenses incurred by attorneys and witnesses, administrative court costs, and any other costs or fees relating to such proceedings.

28. No sooner than five (5) years after entry of this Decree, Defendants may petition FDA for leave to ask this Court for relief from this Decree. If, at the time of the petition, in FDA's judgment, Defendants have maintained a state of continuous compliance with this Decree, the Act, and its implementing regulations for at least five (5) years, Plaintiff will not oppose the petition, and Defendants may request the Court to grant such relief.

29. This Court retains jurisdiction over this action for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED this 14th day of June, 2017.

United States District Judge

We hereby consent to the entry of the foregoing Decree:

FOR DEFENDANTS:

ALBERTO HOYO, individually and on behalf of Stratus Pharmaceuticals, Inc. and Sonar Products, Inc.

JUAN CARLOS BILLOCH, individually and on behalf of Stratus Pharmaceuticals, Inc., and Sonar Products, Inc.

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