



U.S. Department of Justice

Channing D. Phillips  
United States Attorney

*District of Columbia*

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*Judiciary Center  
555 Fourth St., N.W.  
Washington, D.C. 20530*

September 12, 2016

Richard L. Scheff, Esq.  
Montgomery McCracken  
123 South Broad St.  
Philadelphia, PA 19109

Re: United States v. Biocompatibles, Inc.  
Criminal Case No.

Dear Mr. Scheff:

This letter sets forth the full and complete plea offer to your client, BIOCOMPATIBLES, INC. (hereinafter referred to as “your client” or “defendant”), from the Office of the United States Attorney for the District of Columbia and the Consumer Protection Branch, U.S. Department of Justice (hereinafter also referred to as “the Government” or “these Offices”). This plea offer expires on **September 30, 2016**. If your client accepts the terms and conditions of this offer, please have your client execute this document in the space provided below. Upon receipt of the executed document, this letter will become the Plea Agreement (hereinafter referred to as “this Agreement”). The terms of the offer are as follows:

1. **Authorization to Enter this Agreement**

Your client agrees that this Agreement will be executed by an authorized corporate representative. Your client further agrees that a resolution duly adopted by your client’s Board of Directors in the form attached to this Agreement as Exhibit 1, or in similar form, represents that the signatures on this Agreement by your client and its counsel are authorized by your client’s Board of Directors, on behalf of your client. Your client agrees that it has the full legal right, power, and authority to enter into and perform all of its obligations under this Agreement.

2. **Agreement Limited to Parties**

The parties to this agreement are your client and these Offices. This agreement does not provide protections to individuals and entities other than your client: nothing in this Agreement provides any protection against prosecution of any present or former director, officer, employee, shareholder, agent, consultant, reference, contractor, or subcontractor of your client for any violations. Moreover, this agreement does not bind any other branch of the Department of Justice or any other federal, state, or local prosecuting, administrative, or regulatory authority.

3. **Charges and Statutory Penalties**

Your client agrees to plead guilty to a criminal Information, a copy of which is attached, charging your client with one misdemeanor count of causing the introduction and delivery for introduction into interstate commerce of a misbranded medical device, in violation of 21 U.S.C. §§ 331(a) and 333(a)(1). Your client understands that a violation of 21 U.S.C. §§ 331(a) and 333(a)(1) carries a fine of \$200,000 or twice the pecuniary gain or loss of the offense, pursuant to 18 U.S.C. § 3571(c), (d); a term of probation not more than five years; and an obligation to pay any applicable interest or penalties on fines and restitution not timely made. In addition, your client agrees to pay a special assessment of \$125, pursuant to 18 U.S.C. § 3013(a)(1)(B)(iii), to the Clerk of the United States District Court for the District of Columbia.

4. **Factual Stipulations**

Your client agrees that the attached “Statement of Offense” fairly and accurately describes your client’s actions and involvement in the offense to which your client is pleading guilty. Please have your client sign and return the Statement of Offense as a written proffer of evidence, along with this Agreement.

5. **Compliance Agreement**

Your client agrees to comply with the “Compliance Agreement,” attached to this Agreement as Exhibit 2. Please have your client sign and return the Compliance Agreement, along with this Agreement.

6. **Additional Charges**

In consideration of your client’s guilty plea to the above offense, your client will not be further prosecuted criminally by these Offices for the conduct set forth in the attached Statement of Offense.

**7. Agreed Sentence Pursuant to Federal Rule of Criminal Procedure 11(c)(1)(C)**

Pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure, your client and the Government agree to a specific fine in the amount of \$8,751,673, a forfeiture money judgment in the amount of \$2,248,327, and a special assessment of \$125. The Parties agree that this fine of \$8,751,673 and the \$125 special assessment shall be paid to the Clerk of the Court, United States District Court for the District of Columbia, within five (5) business days after sentencing. Your client shall pay the forfeiture amount plus any associated transfer fees within five (5) business days after sentencing, pursuant to payment instructions provided by these Offices in their sole discretion. Your client agrees that it will not claim, assert, or apply for a tax deduction or tax credit with regard to any federal, state, local, or foreign tax for any fine or forfeiture paid pursuant to this agreement.

The Government agrees that it will not seek a separate restitution order as part of the resolution of the charge in the Information. The Government and your client agree that the complication and prolongation of the sentencing process that would result from an attempt to fashion a restitution order outweigh the need to provide restitution to non-governmental victims, if any, in this case.

The Government agrees that it will not seek a term of probation in light of the enhanced corporate rehabilitative compliance measures and certifications required of your client by the attached Compliance Agreement.

Your client and the Government further agree, with the permission of the Court, to waive the requirement of a Pre-Sentence Investigation report pursuant to Federal Rule of Criminal Procedure 32(c)(1)(A)(ii), based on a finding by the Court that the record contains information sufficient to enable the Court to meaningfully exercise its sentencing power. Your client and the Government agree, however, that in the event the Court orders the preparation of a pre-sentence report prior to sentencing, such order will not affect the agreement set forth herein. In the event the Court directs the preparation of a Pre-Sentence Investigation report, these Offices will fully inform the preparer of the pre-sentence report and the Court of the facts and law related to your client's case.

Your client and the Government further agree to ask the Court's permission to combine the entry of the plea and sentencing into one proceeding, and to conduct the plea and sentencing hearings of your client in one proceeding. Your client and the Government agree, however, that in the event the Court orders that the entry of the guilty plea and sentencing hearing occur at separate proceedings, such an order will not affect the agreement set forth herein.

**A. Acceptance of Agreement by the Court**

The Government agrees, pursuant to Rule 11(c)(1)(C), to present this Agreement between the parties to the Court for its approval. In accordance with Rules 11(c)(4) and (5), the Court may accept or reject this Agreement. If the Court accepts this Agreement, the Court will

sentence your client to a specific fine in the amount of \$8,751,673, a forfeiture money judgment in the amount of \$2,248,327, and a special assessment of \$125. Your client understands that if the Court accepts this Agreement, then the Court will embody in the judgment and sentence the disposition provided for in this Agreement, pursuant to Rule 11(c)(4) of the Federal Rules of Criminal Procedure.

## **B. Rejection of this Agreement by the Court**

The parties understand that the Court may not agree that the sentence agreed to by the parties is an appropriate one and may reject this Agreement pursuant to Rule 11(c)(5) of the Federal Rules of Criminal Procedure. Your client understands that if this happens, the Court, in accordance with the requirements of Rule 11(c)(5), will inform the parties of its rejection of this Agreement, and will afford your client an opportunity to withdraw the plea or maintain the plea. If your client elects to maintain the plea, the Court will inform your client that a final disposition may be less favorable to your client than that contemplated by this Agreement. Your client further understands that if the Court rejects this Agreement, the Government also has the right to withdraw from this Agreement and to be freed from all obligations under this Agreement, and may in its sole discretion bring different or additional charges before your client enters any guilty plea in this case.

If the Court rejects this Agreement, your client elects to maintain this plea, and the Government does not exercise its right to withdraw from this Agreement, the parties agree that your client will be sentenced upon consideration of the factors set forth in 18 U.S.C. § 3553(a) and the Sentencing Guidelines. Your client further understands that, in such case, the sentence to be imposed is a matter solely within the discretion of the Court, and the Court is not obligated to impose a sentence within the Sentencing Guidelines range or to follow any recommendation of the Government at the time of sentencing.

## **8. Sentencing Guidelines Analysis**

In accordance with Paragraph 7 above, your client understands that, but for the above described agreed sentence pursuant to Rule 11(c)(1)(C), the sentence in this case would be determined by the Court, pursuant to the factors set forth in 18 U.S.C. § 3553(a), including a consideration of the Sentencing Guidelines and policies promulgated by the Sentencing Guidelines. Your client and the Government parties agree that while the fine provisions of the United States Sentencing Guidelines Manual do not apply to organizational defendants for misdemeanor violations of the Food, Drug, and Cosmetic Act, see U.S.S.G. § 8C2.1, the agreed upon fine is consonant with the Guidelines and takes into account your client's conduct under 18 U.S.C. §§ 3553 and 3572 and U.S.S.G. § 8C2.10, as follows:

- a. the pecuniary gain to the defendant from the offense is \$8,751,673;

- b. taking into account the nature and circumstances of the offense and a multiplier of 1.0, which your client and the Government agree is appropriate in this case;
- c. the resulting criminal fine is \$8,751,673; and
- d. this agreed upon fine falls within the statutory maximum set forth in 18 U.S.C. § 3571(d) (twice the gross gain or loss). Your client and the Government further agree that disgorgement pursuant to U.S.S.G. § 8C2.9 is unnecessary, and there is no basis for a downward departure or deviation under the United States Sentencing Guidelines.

9. **Reservation of Allocution**

The Government and your client reserve the right to describe fully, both orally and in writing, to the sentencing judge, the nature and seriousness of your client's misconduct, including any misconduct not described in the charges to which your client is pleading guilty. The parties also reserve the right, in the event a Pre-Sentence Investigation Report is prepared, to inform the presentence report writer and the Court of any relevant facts, to dispute any factual inaccuracies in the presentence report, and to contest any matters not provided for in this Agreement. In the event that the Court considers any Sentencing Guidelines adjustments, departures, or calculations different from any agreements contained in this Agreement, or contemplates a sentence outside the Guidelines range based upon the general sentencing factors listed in 18 U.S.C. § 3553(a), the parties reserve the right to answer any related inquiries from the Court. In addition, if in this Agreement the parties have agreed to recommend or refrain from recommending to the Court a particular resolution of any sentencing issue, the parties reserve the right to full allocution in any post-sentence litigation. The parties retain the full right of allocution in connection with any post-sentence motion which may be filed in this matter.

10. **Waivers**

Your client waives any challenge to venue in the District of Columbia.

11. **Statute of Limitations**

Your client agrees that, should the conviction following your client's plea of guilty pursuant to this Agreement be vacated for any reason, any prosecution, based on the conduct set forth in the attached Statement of Offense, that is not time-barred by the applicable statute of limitations on the date of the signing of this Agreement may be commenced or reinstated against your client, notwithstanding the expiration of the statute of limitations between the signing of this Agreement and the commencement or reinstatement of such prosecution. It is the intent of this Agreement to waive all defenses based on the statute of limitations with respect to any

prosecution of conduct set forth in the attached Statement of Offense that is not time-barred on the date that this Agreement is signed.

12. **Trial Rights**

Your client understands that by pleading guilty in this case your client agrees to waive certain rights afforded by the Constitution of the United States and/or by statute or rule. Your client agrees to forego the right to any further discovery or disclosures of information not already provided at the time of the entry of your client's guilty plea. Your client also agrees to waive, among other rights, the right to plead not guilty and the right to a jury trial. If there were a jury trial, your client would have the right to be represented by counsel, to confront and cross-examine witnesses against your client, and to compel witnesses to appear for the purpose of testifying and presenting other evidence on your client's behalf. Your client would further have the right to have the jury instructed that your client is presumed innocent until proven guilty, and that the burden would be on the United States to prove your client's guilt beyond a reasonable doubt. If your client were found guilty after a trial, your client would have the right to appeal your client's conviction.

Your client acknowledges discussing with you Rule 11(f) of the Federal Rules of Criminal Procedure and Rule 410 of the Federal Rules of Evidence, which ordinarily limit the admissibility of statements made by a defendant in the course of plea discussions or plea proceedings if a guilty plea is later withdrawn. Your client knowingly and voluntarily waives the rights that arise under these rules in the event your client withdraws your client's guilty plea or withdraws from this Agreement after signing it.

Your client also agrees to waive all constitutional and statutory rights to a speedy sentence and agrees that the plea of guilty pursuant to this Agreement will be entered at a time decided upon by the parties with the concurrence of the Court. Your client understands that the date for sentencing will be set by the Court.

13. **Appeal Rights**

Your client understands that federal law, specifically 18 U.S.C. § 3742, affords defendants the right to appeal their sentences in certain circumstances. Your client agrees to waive the right to appeal the sentence in this case, including any fine, forfeiture, award of restitution, term of probation, and the manner in which the sentence was determined, except to the extent the Court sentences your client above the statutory maximum or guidelines range determined by the Court or your client claims that your client received ineffective assistance of counsel, in which case your client would have the right to appeal the illegal sentence or above-guidelines sentence or raise on appeal a claim of ineffective assistance of counsel, but not to raise on appeal other issues regarding the sentencing. In agreeing to this waiver, your client is aware that your client's sentence has yet to be determined by the Court. Realizing the uncertainty in estimating what sentence the Court ultimately will impose, your client knowingly

and willingly waives your client's right to appeal the sentence, to the extent noted above, in exchange for the concessions made by the Government in this Agreement.

14. **Collateral Attack**

Your client also waives any right to challenge the conviction entered or sentence imposed under this Agreement or otherwise attempt to modify or change the sentence or the manner in which it was determined in any collateral attack, including, but not limited to, a motion brought under 28 U.S.C. § 2255 or Federal Rule of Civil Procedure 60(b), except to the extent such a motion is based on newly discovered evidence or on a claim that your client received ineffective assistance of counsel. Your client reserves the right to file a motion brought under 18 U.S.C. § 3582(c)(2).

15. **Privacy Act and FOIA Rights**

Your client also agrees to waive all rights, whether asserted directly or by a representative, to request or receive from any department or agency of the United States any records pertaining to the investigation or prosecution of this case, including and without limitation any records that may be sought under the Freedom of Information Act, 5 U.S.C. § 552, or the Privacy Act, 5 U.S.C. § 552a.

16. **Restitution**

Your client understands that the Court has an obligation to determine whether, and in what amount, mandatory restitution applies in this case under 18 U.S.C. § 3663A. The Government and your client agree that the complication and prolongation of the sentencing process that would result from an attempt to fashion a restitution order outweigh the need to provide restitution to non-governmental victims, if any, in this case.

Your client certifies that your client has made no transfer of assets in contemplation of this prosecution for the purpose of evading or defeating financial obligations that are created by this Agreement and/or that may be imposed by the Court. In addition, your client promises to make no such transfers in the future until your client has fulfilled the financial obligations under this Agreement.

17. **Forfeiture**

(a) Your client agrees to the forfeiture set forth in the Forfeiture Allegation in the Criminal Information to which your client is pleading guilty. Your client also agrees to the entry of a forfeiture money judgment in the amount of \$2,248,327. Your client agrees to pay the forfeiture money judgment, plus any associated transfer fees, at or before sentencing, pursuant to payment instructions provided by the government.

(b) Your client agrees that the proffer of evidence supporting your client's guilty plea is sufficient evidence to support this forfeiture. Your client agrees that the Court may enter a preliminary Consent Order of Forfeiture for this property at the time of your client's guilty plea or at any time before sentencing. Your client agrees that this Order will become final as to your client when it is issued and will be a part of the sentence pursuant to Federal Rule of Criminal Procedure 32.2(b)(4)(A).

(c) Your client agrees that this plea agreement permits the government to seek to forfeit any of your client's assets, real or personal, that are subject to forfeiture under any federal statute, whether or not this agreement specifically identifies the asset. Regarding any asset or property, your client agrees to forfeiture of all interest in: (1) any property, real or personal, which constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of the offense; (2) any medical device that is misbranded when introduced into or while in interstate commerce or while held for sale after shipment in interstate commerce, or which may not, under the provisions of Title 21, United States Code, Section 331, be introduced into interstate commerce; and (3) any substitute assets for property otherwise subject to forfeiture. *See* 18 U.S.C. 982(a)(7); 21 U.S.C. §§ 334 and 853(p); 28 U.S.C. § 2461(c).

(d) Your client agrees that the government may choose in its sole discretion how it wishes to accomplish forfeiture of the property whose forfeiture your client has consented to in this plea agreement, whether by criminal or civil forfeiture, using judicial or non-judicial forfeiture processes. If the government chooses to effect the forfeiture provisions of this plea agreement through the criminal forfeiture process, your client agrees to the entry of orders of forfeiture for such property and waives the requirements of Federal Rule of Criminal Procedure 32.2 regarding notice of the forfeiture in the charging instrument, announcement of the forfeiture at sentencing, and incorporation of the forfeiture in the judgment. Your client understands that the forfeiture of assets is part of the sentence that may be imposed in this case.

(e) Your client agrees that, if it does not pay the forfeiture money judgment at or before sentencing, this Plea Agreement permits the Government to take all necessary actions to identify all assets over which your client exercises or exercised control, directly or indirectly, at any time since May 1, 2006, or in which your client has or had during that time any financial interest. Your client agrees in such case to take all steps as requested by the Government to obtain from any other parties by any lawful means any records of assets owned at any time by your client. Your client further agrees in such case to provide and/or consent to the release of your client's tax returns for the previous five years. Your client also agrees to take all steps as requested by the Government to pass clear title to forfeitable interests or to property to the United States and to testify truthfully in any judicial forfeiture proceeding.

(f) Your client agrees to waive all constitutional and statutory challenges in any manner (including, but not limited to, direct appeal) to any forfeiture carried out in accordance with this plea agreement on any grounds, including that the forfeiture constitutes an excessive fine or punishment.



18. **Public Statements by Your Client**

Your client expressly agrees that it shall not, through its present or future attorneys, board of directors, agents, officers or employees, agents or any other person authorized to speak for your client, make any public statement, in litigation or otherwise, contradicting the acceptance of responsibility by your client set forth above or the facts described in the Statement of Offense. Any such contradictory statement shall, subject to cure rights of your client described below, constitute a breach of this Agreement and your client thereafter shall be subject to prosecution as set forth in Paragraph 21 of this Agreement. The decision whether any public statement by any such person contradicting a fact contained in the Statement of Offense will be imputed to your client for the purpose of determining whether it has breached this Agreement shall be at the sole discretion of these Offices. If these Offices determine that a public statement by any such person contradicts in whole or in part a statement contained in the Statement of Offense, these Offices shall so notify your client, and your client may avoid a breach of this Agreement by publicly repudiating such statement(s) within five business days after notification. Notwithstanding the above and consistent with the obligations of your client as set forth above, your client shall be permitted to raise defenses and to assert affirmative claims in civil and regulatory proceedings related to the matters set forth in the Statement of Offense. This paragraph does not apply to any statement made by any present or former employee of your client in the course of any criminal, regulatory or civil case initiated against such individual, unless such individual is speaking on behalf of your client.

19. **Sale or Merger of Your Client**

Your client agrees that in the event that it sells, merges or transfers all or substantially all of its business operations as they exist as of the date of this Agreement, whether such sale is structured as a stock or asset sale, merger or transfer, it shall include in any contract for sale, merger or transfer a provision binding the purchaser, or any successor in interest thereto, to the obligations described in this Agreement.

20. **Debarment and Notice to Law Enforcement and Regulatory Authorities**

Your client understands that it may be subject to suspension or debarment action by state agencies or federal agencies other than these Offices based upon entering into this Agreement, and that this Agreement in no way controls what action, if any, other agencies may take. Your client affirms that it wants to enter into this Agreement regardless of any suspension or debarment consequences. These Offices agree, if requested to do so, to bring to the attention of law enforcement and regulatory authorities, to include debarment authorities, the facts and circumstances relating to the nature of the conduct underlying this Agreement, including the nature and quality of your client's cooperation and remediation. By agreeing to provide this information to such authorities, these Offices are not agreeing to advocate on behalf of your client, but rather are agreeing to provide information to be evaluated independently by such authorities.

21. **Breach of Agreement**

Your client understands and agrees that, if after entering this Agreement, your client fails specifically to perform or to fulfill completely each and every one of your client's obligations under this Agreement, including but not limited to fulfilling the requirements of the Compliance Agreement referenced in Paragraph 5, or engages in any criminal activity prior to sentencing, your client will have breached this Agreement. In the event of such a breach: (a) the Government will be free from its obligations under this Agreement; (b) your client will not have the right to withdraw the guilty plea; (c) your client will be fully subject to criminal prosecution for any other crimes, including perjury and obstruction of justice; and (d) the Government will be free to use against your client, directly and indirectly, in any criminal or civil proceeding, all statements made by your client and any of the information or materials provided by your client, including such statements, information and materials provided pursuant to this Agreement or during the course of any debriefings conducted in anticipation of, or after entry of, this Agreement, whether or not the debriefings were previously characterized as "off-the-record" debriefings, and including your client's statements made during proceedings before the Court pursuant to Rule 11 of the Federal Rules of Criminal Procedure.

Your client understands and agrees that the Government shall be required to prove a breach of this Agreement only by a preponderance of the evidence, except where such breach is based on a violation of federal, state, or local criminal law, which the Government need prove only by probable cause in order to establish a breach of this Agreement.

Nothing in this Agreement shall be construed to permit your client to commit perjury, to make false statements or declarations, to obstruct justice, or to protect your client from prosecution for any crimes not included within this Agreement or committed by your client after the execution of this Agreement. Your client understands and agrees that the Government reserves the right to prosecute your client for any such offenses. Your client further understands that any perjury, false statements or declarations, or obstruction of justice relating to your client's obligations under this Agreement shall constitute a breach of this Agreement. In the event of such a breach, your client will not be allowed to withdraw your client's guilty plea.

22. **Complete Agreement**

No agreements, promises, understandings, or representations have been made by the parties or their counsel other than those contained in writing herein, nor will any such agreements, promises, understandings, or representations be made unless committed to writing and signed by you, your client, an Assistant United States Attorney for the District of Columbia, and a Trial Attorney for the Consumer Protection Branch.

Your client further understands that this Agreement is binding only upon the Criminal Division of the United States Attorney's Office for the District of Columbia. This Agreement

does not bind the Civil Division of the United States Attorney's Office for the District of Columbia, any other United States Attorney's Office, or the Civil Division of the Department of Justice. The Offices understand though, that your client has entered, or will enter, into a separate written settlement agreement with the Civil Division of the Department of Justice, the Civil Division of the United States Attorney's Office for the District of Columbia, and the Civil Division of the United States Attorney's Office for the Western District of Texas on claims that are related to, but not fully commensurate with, the conduct addressed herein. Furthermore, this Agreement does not bind any other state, local, or federal prosecutor. It also does not bar or compromise any civil, tax, or administrative claim pending or that may be made against your client.

If the foregoing terms and conditions are satisfactory, your client may so indicate by signing this Agreement and the Statement of Offense, and returning both to me no later than **September 30, 2016**.

Sincerely yours,



CHANNING D. PHILLIPS  
United States Attorney



Virginia Cheatham  
Assistant United States Attorney  
555 Fourth St., N.W., Fifth Floor  
Washington, D.C. 20530  
Bar No. DC – 411980  
202-252-7820  
[virginia.cheatham@usdoj.gov](mailto:virginia.cheatham@usdoj.gov)



Patrick Jasperse  
Senior Litigation Counsel  
U.S. Department of Justice  
Consumer Protection Branch  
450 Fifth St., N.W., Sixth Floor South  
Washington, D.C. 20001  
555 Fourth St., N.W., Fifth Floor  
Washington, D.C. 20530  
D.C. Bar Number 986804  
202-616-0509  
[patrick.jasperse@usdoj.gov](mailto:patrick.jasperse@usdoj.gov)

**COMPANY OFFICER'S CERTIFICATE**

I have read this Agreement and carefully reviewed every part of it with outside counsel for BIOCOMPATIBLES, INC. ("BIOCOMPATIBLES"). I understand the terms of this Agreement and voluntarily agree, on behalf of BIOCOMPATIBLES, to each of its terms. Before signing this Agreement, I consulted outside counsel for BIOCOMPATIBLES. Counsel fully advised me of the rights of BIOCOMPATIBLES, of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into this Agreement.

I have carefully reviewed the terms of this Agreement with the Board of Directors of BIOCOMPATIBLES. I have caused outside counsel for BIOCOMPATIBLES to advise the Board of Directors fully of the rights of BIOCOMPATIBLES, of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into the Agreement.

No promises or inducements have been made other than those contained in this Agreement. Furthermore, no one has threatened or forced me, or to my knowledge any person authorizing this Agreement on behalf of BIOCOMPATIBLES, in any way to enter into this Agreement. I am also satisfied with outside counsel's representation in this matter. I certify that I am the President of BIOCOMPATIBLES and that I have been duly authorized by BIOCOMPATIBLES to execute this Agreement on behalf of BIOCOMPATIBLES.

Date: 10/4/16

BIOCOMPATIBLES, INC.

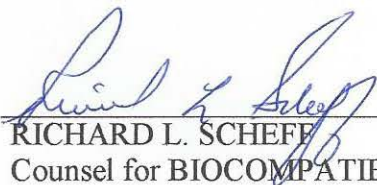
By:

  
\_\_\_\_\_  
KEN PUGH  
PRESIDENT of BIOCOMPATIBLES, INC.

## CERTIFICATE OF COUNSEL

I am counsel for BIOCOMPATIBLES, INC., ("BIOCOMPATIBLES") in the matter covered by this Agreement. In connection with such representation, I have examined relevant BIOCOMPATIBLES documents and have discussed the terms of this Agreement with BIOCOMPATIBLES' Board of Directors. Based on our review of the foregoing materials and discussions, I am of the opinion that the representative of BIOCOMPATIBLES has been duly authorized to enter into this Agreement on behalf of BIOCOMPATIBLES and that this Agreement has been duly and validly authorized, executed, and delivered on behalf of BIOCOMPATIBLES and is a valid and binding obligation of BIOCOMPATIBLES. Further, I have carefully reviewed the terms of this Agreement with the Board of Directors and the President of BIOCOMPATIBLES. I have fully advised them of the rights of BIOCOMPATIBLES, of possible defenses, of the Sentencing Guidelines' provisions and of the consequences of entering into this Agreement. To my knowledge, the decision of BIOCOMPATIBLES to enter into this Agreement, based on the authorization of the Board of Directors, is an informed and voluntary one.

Date: 10/5/16

By:   
RICHARD L. SCHEFF  
Counsel for BIOCOMPATIBLES, INC.

## EXHIBIT 1

### CERTIFICATE OF CORPORATE RESOLUTIONS

WHEREAS, BIOCOMPATIBLES, INC., (the "Company") has been engaged in discussions with the United States Attorney's Office for the District of Columbia and the Consumer Protection Branch, U.S. Department of Justice ("these Offices") regarding violations of the Food, Drug, and Cosmetic Act; and

WHEREAS, in order to resolve such discussions, it is proposed that the Company enter into a certain agreement with the Office; and

WHEREAS, the Company's President, Ken Pugh, together with outside counsel for the Company, have advised the Board of Directors of the Company of its rights, possible defenses, the Sentencing Guidelines' provisions, and the consequences of entering into such agreement with the Office;

Therefore, the Board of Directors has RESOLVED that:

1. The Company (a) acknowledges the filing of the one-count Information charging the Company with causing the introduction and delivery for introduction of a misbranded medical device into interstate commerce, in violation of Title 21, United States Code, Sections 331(a) and 333(a)(1); (b) waives indictment on such a charge and enters into a Rule 11(c)(1)(C) plea agreement with these Offices; (c) agrees to pay a criminal fine of \$8,751,673; and (d) agrees to forfeit \$2,248,327 with respect to the conduct described in the Information.
2. The Company accepts the terms and conditions of this Agreement, including, but not limited to, (a) a knowing waiver of its rights to a speedy trial pursuant to the Sixth Amendment to the United States Constitution, Title 18, United States Code, Section 3161, and Federal Rule of Criminal Procedure 48(b); and (b) a knowing waiver for purposes of this

Agreement and any charges by the United States arising out of the conduct described in the attached Statement of Offense of any objection with respect to venue and consents to the filing of the Information, as provided under the terms of this Agreement, in the United States District Court for the District of Columbia; and (c) a knowing waiver of any defenses based on the statute of limitations for any prosecution relating to the conduct described in the attached Statement of Offense or relating to conduct known to the Office prior to the date on which this Agreement was signed that is not time-barred by the applicable statute of limitations on the date of the signing of this Agreement;

3. The President, Ken Pugh, is hereby authorized, empowered and directed, on behalf of the Company, to execute the Rule 11(c)(1)(C) plea agreement substantially in such form as reviewed by this Board of Directors at this meeting with such changes as President, Ken Pugh, may approve;

4. President, Ken Pugh, is hereby authorized, empowered and directed to take any and all actions as may be necessary or appropriate and to approve the forms, terms or provisions of any agreement or other documents as may be necessary or appropriate, to carry out and effectuate the purpose and intent of the foregoing resolutions; and

5. All of the actions of President, Ken Pugh, which actions would have been authorized by the foregoing resolutions except that such actions were taken prior to the adoption of such resolutions, are hereby severally ratified, confirmed, approved, and adopted as actions on behalf of the Company.

Date: 10/5/16

By: Valerie Mattis  
[NAME] Valerie Mattis  
Corporate Secretary  
BIOCOMPATIBLES, INC.