IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEVADA

UNITED STATES OF AMERICA, Plaintiff, v. STEINER BIOTECHNOLOGY LLC, a limited liability company, and GREGORY G. STEINER and ROSLYNN L. STEINER, individuals, Defendants.	)	Civil Action No. 2:26-cv-2410

COMPLAINT FOR PERMANENT INJUNCTION

The United States of America, Plaintiff, by and through its undersigned counsel, and on behalf of the United States Food and Drug Administration ("FDA"), respectfully represents as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act ("FDCA" or the "Act"), 21 U.S.C. § 332(a), to permanently enjoin the defendants, Steiner Biotechnology, LLC ("SteinerBio"), a limited liability company, and Gregory G. Steiner and Roslynn L. Steiner, individuals (collectively, "Defendants") from violating:

A. 21 U.S.C. § 331(a) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce,

devices, as defined by 21 U.S.C. § 321(h), that are adulterated within the meaning of the FDCA as follows:

i. 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls use for, their manufacture, packing, storage, and installation are not in conformity with current good manufacturing practice ("CGMP") requirements prescribed at 21 C.F.R. Part 820; and

ii. 21 U.S.C. § 351(f)(1)(B), in that certain devices are Class III devices pursuant to 21 U.S.C. § 360c(f), and there are no approved applications for premarket approval ("PMAs") on file with FDA as required by 21 U.S.C. § 360e(a), and the devices do not have an approved application for an investigational device exemption under 21 U.S.C. § 360j(g).

B. 21 U.S.C. § 331(a), by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce, devices, as defined by 21 U.S.C. § 321(h), that are misbranded within the meaning of 21 U.S.C. § 352(o), in that Defendants failed to provide notice or other information respecting certain devices to FDA as required by 21 U.S.C. § 360(k).

C. 21 U.S.C. § 331(k), by causing devices to become adulterated within the meaning of 21 U.S.C. §§ 351(h) and/or 351(f)(1)(B), as described in paragraph A above, and misbranded within the meaning of 21 U.S.C. § 352(o), as

described in paragraph B above, while such devices are held for sale after shipment of one or more of their components in interstate commerce.

Jurisdiction and Venue

2. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1337, and 1345, and 21 U.S.C. § 332(a), and has personal jurisdiction over all parties.

3. Venue in this district is proper under 28 U.S.C. § 1391(b) and (c).

Defendants

4. Defendant SteinerBio is a Nevada limited liability company located at 1051 Olsen Street, Suite 3611, Henderson, Nevada 89011 ("the facility"), within the jurisdiction of this Court. SteinerBio manufactures medical devices primarily intended for dental use, including synthetic bone graft materials and dental cement.

5. Defendant Gregory G. Steiner is the co-owner and Chief Executive Officer of SteinerBio. As the top management official, he is responsible for the overall operation of the firm including providing resources, handling audits, and manufacturing. Defendant Gregory Steiner is based in Hawaii and is physically present at the facility part time.

6. Defendant Roslynn L. Steiner is the President and co-owner of SteinerBio. In that capacity, she oversees firm operations along with Defendant Gregory Steiner, including product and process operations, and has the power and

authority to detect and prevent quality problems. Defendant Roslynn Steiner is based in Hawaii and is physically present at the facility part time.

7. Defendants manufacture various devices, as defined by 21 U.S.C. § 321(h), including, but not limited to, the following: Socket Graft Plus; Socket Graft Injectable; Immediate Graft; BioDensification; Ridge Graft Kit; Sinus Graft; OsseoConduct; and Oral Bond.

8. Defendants manufacture devices using components that were shipped in interstate commerce, including from Utah and New York.

9. Defendants ship their devices in interstate commerce to customers, primarily dentists and dental practices, throughout the United States.

Legal Standards

10. A device must be manufactured, packed, stored, and installed in conformity with good manufacturing practice to ensure its safety and effectiveness. 21 U.S.C. § 360j(f).

11. The quality management system ("QMS") regulation for devices, 21 C.F.R. Part 820, sets the minimum requirements for compliance with CGMP. The QMS regulation became effective on February 2, 2026, replacing the Quality System ("QS") regulation (also 21 C.F.R. Part 820).

12. A device that has been manufactured, packed, stored, or installed in violation of a QMS regulation or a QS regulation is deemed to be adulterated. 21 U.S.C. § 351(h).

13. FDA's oversight of medical devices is risk-based, which means that the level of regulatory controls necessary to demonstrate a reasonable assurance of safety and effectiveness is typically matched to the level of risk of the device. As device class increases the regulatory controls also increase. Class I devices are subject to the least regulatory control, while Class III devices are subject to the most stringent regulatory control. With certain exceptions, Class III devices must have an approved application for Premarket Approval ("PMA") prior to marketing. 21 U.S.C. §§ 360c(f)(1), 360e(a).

14. Virtually all devices introduced or delivered for introduction into interstate commerce for commercial distribution after May 28, 1976, are automatically classified as Class III as a matter of law, 21 U.S.C. § 360c(f)(1). The sponsor of a device may avoid this automatic statutory Class III designation, and thereby avoid the PMA process, only if it obtains an order from FDA reclassifying the device into Class I or Class II, or an order finding that the device is "substantially equivalent" to a legally-marketed predicate device that does not require premarket approval (commonly known as a cleared 510(k) premarket

notification submission or "510(k)"). 21 U.S.C. §§ 360c(f), 360e(a) and (b), 360(k).

15. A Class III device is adulterated if: (1) it is required to have in effect an approved application for PMA under 21 U.S.C. § 360e(a); (2) there is no FDA-approved PMA application in effect; and (3) it is not exempt from premarket approval as an investigational device under 21 U.S.C. § 360j(g). 21 U.S.C. § 351(f)(1)(B).

16. Premarket notification is required for any device that is currently in commercial distribution, but is significantly changed or modified in its design, components, methods of manufacture, or intended use. 21 C.F.R. § 807.81(a)(3). Specifically, premarket notification is required if a device presents: (a) a change in its design or chemical composition that could significantly affect its safety or effectiveness, 21 C.F.R. § 807.81(a)(3)(i); or (b) a major change or modification in its intended use, 21 C.F.R. § 807.81(a)(3)(ii).

17. Under the Act, a device is misbranded if a person who is required to register pursuant to 21 U.S.C. § 360 and proposes to introduce a device into interstate commerce for commercial distribution fails to submit to FDA a premarket notification submission. 21 U.S.C. § 352(o).

18. The introduction or delivery for introduction into interstate commerce of an adulterated or misbranded device is a violation of the Act, 21 U.S.C. § 331(a).

19. The adulteration and misbranding of a device while it is held for sale after shipment in interstate commerce constitutes a violation of the Act, 21 U.S.C. § 331(k).

Legal Status of Defendants' Products

20. Defendants market their products, among other places, on their website, www.steinerbio.com. Defendants' website includes links for "Instructions for Use" for each product, available as a PDF. Defendants' website also offers its products for purchase online. Defendants are responsible for the management and content of their website.

21. The "Instructions for Use" for the Socket Graft Plus, Socket Graft Injectable, and Immediate Graft products state they are "ready to use" and no mixing is required.

22. Defendants claim on their website that their Socket Graft Plus, Socket Graft Injectable, Immediate Graft, BioDensification, Ridge Graft Kit, and Sinus Graft products "provide[] the organic and inorganic molecules a bone needs in order to regrow faster, stronger, healthier, and more vital . . . . SL Factor in [Defendants'] bone graft material targets the osteoblasts within the patient's bone,

initiating the bone regeneration process." Defendants' website describes "SL Factor" as a component that "changes the physiology of a bone's osteoblasts to stimulate osteogenesis" and that their products containing SL Factor are intended for uses such as "initiating the bone regeneration process," "stimulating bone growth," and reducing inflammation.

23. Defendants' products are devices within the meaning of 21 U.S.C. § 321(h), in that they are intended (a) for the use in the cure, mitigation, treatment, or prevention of disease, and/or (b) to affect the structure or any function of the body of man.

24. Insofar as any of Defendants' products are combination products within the meaning of 21 U.S.C. § 353(g)(1) and 21 C.F.R. § 3.2(e)(1), those products are regulated as devices according to 21 C.F.R. § 3.4(b).

25. Defendants have three cleared 510(k) premarket notification submissions for three synthetic bone graft device products: K113049; K101718; and K063010.

2025 Inspection

26. FDA inspected Defendants' facility between February 3-14, 2025. This inspection revealed numerous violations of the Act and its implementing regulations, including that Defendants were distributing adulterated and

misbranded devices. Specifically, the FDA investigators documented the following violations with respect to one of more of Defendants' devices:

A. Defendants fail to comply with the QS regulation set forth in 21 C.F.R. Part 820, as follows:

i. Defendants fail to establish and maintain adequate procedures to control the design of the devices in order to ensure that specified design requirements are met, as required by 21 C.F.R. § 820.30(a);

ii. Defendants fail to adequately validate processes according to established procedures, where the results of such processes cannot be fully verified by subsequent inspection and test, as required by 21 C.F.R. § 820.75(a);

iii. Defendants fail to establish and maintain adequate procedures for validating the device design, including risk analysis, as required by 21 C.F.R. § 820.30(g);

iv. Defendants fail to establish and maintain procedures to adequately control environmental conditions, as required by 21 C.F.R. § 820.70(c); and

v. Defendants fail to establish and maintain adequate procedures to fully investigate the cause of nonconformities relating to product, processes, and the quality system; to adequately identify the action(s) needed to

correct and prevent recurrence of nonconforming product and other quality problems; to adequately verify or validate the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device; and adequately submit relevant information on identified quality problems, as well as corrective and preventive actions, for management review, as required by 21 C.F.R. § 820.100(a)(2), (3), (4), (7).

B. Defendants are distributing Class III devices, under 21 U.S.C. § 360c(f), for which they do not have an approved application for PMA pursuant to 21 U.S.C. § 360e(a) or a cleared 510(k) pursuant to 21 U.S.C. § 360(k), nor do they have an approved application for an investigational device exemption under 21 U.S.C. § 360j(g).

i. Defendants assert two cleared 510(k)s for Socket Graft Plus: K113049 and K101718. But changes have been made to the Socket Graft Plus device's chemical composition and design that could significantly affect the device's safety or effectiveness, and Defendants have neither received FDA approval of a PMA application for the modified device nor obtained clearance of a 510(k) for the modified device, as required by 21 C.F.R. § 807.81(a)(3)(i). Further, Defendants are making intended use claims for the Socket Graft Plus device that are not in the cleared 510(k)s and constitute a major change or modification in the device's intended use, but Defendants have neither received FDA approval of a

PMA application for the currently marketed device nor obtained clearance of a 510(k) for the new intended uses for the device, as required by 21 C.F.R. § 807.81(a)(3)(ii).

ii. Defendants assert two cleared 510(k)s for Socket Graft Injectable: K113049 and K10718. Defendants have changed the Socket Graft Injectable device's chemical composition and design such that the changes could significantly affect the device's safety or effectiveness, but Defendants have neither received FDA approval of a PMA application for the modified device nor obtained clearance of a 510(k) for the modified device, as required by 21 C.F.R. § 807.81(a)(3)(i). Further, Defendants are making claims for the Socket Graft Injectable device that are not in the cleared 510(k)s and constitute a major change or modification in the device's intended use, but Defendants have neither received FDA approval of a PMA application for the currently marketed device nor obtained clearance of a 510(k) for the new intended uses for the device, as required by 21 C.F.R. § 807.81(a)(3)(ii).

iii. Defendants assert two cleared 510(k)s for Immediate Graft: K113049 and K10718. Defendants have changed the Immediate Graft device's chemical composition and design such that the changes could significantly affect the device's safety or effectiveness, but Defendants have neither received FDA approval of a PMA application for the modified device nor

obtained clearance of a 510(k) for the modified device, as required by 21 C.F.R. § 807.81(a)(3)(i). Further, Defendants are making claims for the Immediate Graft device that are not in the cleared 510(k)s and constitute a major change or modification in the device's intended use, but Defendants have neither received FDA approval of a PMA application for the currently marketed device nor obtained clearance of a 510(k) for the new intended uses for the device, as required by 21 C.F.R. § 807.81(a)(3)(ii).

iv. Defendants assert a cleared 510(k) for BioDensification: K113049. Defendants are making claims for the BioDensification device that are not in the cleared 510(k) and constitute a major change or modification in the device's intended use, but Defendants have neither received FDA approval of a PMA application for the currently marketed device nor obtained clearance of a 510(k) for the new intended uses for the device, as required by 21 C.F.R. § 807.81(a)(3)(ii).

v. Defendants assert one cleared 510(k) for Ridge Graft Kit: K101718. Defendants are making claims for the Ridge Graft Kit that are not in the cleared 510(k) and constitute a major change or modification in the device's intended use, but Defendants have neither received FDA approval of a PMA application for the currently marketed device nor obtained clearance of a 510(k)

for the new intended uses for the device, as required by 21 C.F.R. § 807.81(a)(3)(ii).

vi. Defendants assert one cleared 510(k) for Sinus Graft: K063010. Defendants are making claims for the Sinus Graft device that are not in the cleared 510(k) and constitute a major change or modification in the device's intended use, but Defendants have neither received FDA approval of a PMA application for the currently marketed device nor obtained clearance of a 510(k) for the new intended uses for the device, as required by 21 C.F.R. § 807.81(a)(3)(ii).

27. All of the violations of the QS regulation described above are violations of the QMS regulation.

28. At the conclusion of the 2025 inspection, FDA investigators issued a List of Inspectional Observations ("Form FDA 483") to Defendant Roslynn Steiner, detailing Defendants' violations of the Act and discussed the documented observations with her.

Prior Inspections

29. FDA inspected Defendants' facility numerous times prior to the 2025 inspection including inspections conducted between December 10-13, 2018; August 15-19, 2022; November 3-8, 2022; and January 22 through February 1, 2024.

30. During the 2018, November 2022, and 2024 inspections, FDA investigators observed numerous violations of the QS regulation that were the same as or similar to those described in paragraph 26.A above, including but not limited to, violations involving the following: design controls (21 C.F.R. § 820.30); process validation (21 C.F.R. § 820.75); corrective and preventative action (21 C.F.R. § 820.100); and production and process controls (21 C.F.R. § 820.70). These violations of the QS regulation are violations under the QMS regulation.

31. At the conclusion of the 2018, November 2022, and 2024 inspections, FDA investigators issued to the most responsible person at the firm a Form FDA 483 detailing FDA's observations and discussed the documented observations with the recipient.

Prior Notice of Violations

32. Defendants are well aware that their practices violate the Act. FDA has repeatedly warned Defendants, both orally and in writing, about their violative conduct, and has emphasized the importance of Defendants' compliance with the Act.

33. Following FDA's 2018 inspection of Defendants' facility, FDA issued a letter to SteinerBio and Defendant Gregory Steiner on April 3, 2019, explaining

that the firm's devices are adulterated within the meaning of the Act, 21 U.S.C. § 351(h).

34. Following FDA's November 3-8, 2022 inspection, FDA issued a Warning Letter to SteinerBio and Defendant Gregory Steiner dated May 19, 2023, explaining that the firm's devices are adulterated within the meaning of the Act, 21 U.S.C. § 351(h), and also that some of its devices are also adulterated within the meaning of the Act, 21 U.S.C. § 351(f)(1)(B).

35. On August 20, 2024, FDA met with Defendants Gergory and Roslynn Steiner to discuss FDA's ongoing concerns.

36. Despite numerous warnings from FDA over the past seven years and Defendants' repeated promises to correct the numerous ongoing violations, Defendants continue to violate the Act, as observed in FDA's most recent inspection.

37. Based on Defendants' conduct, Plaintiff believes that, unless restrained by order of this Court, Defendants will continue to violate 21 U.S.C. §§ 331(a) and (k).

COUNT I

(21 U.S.C. § 331(a))

38. Paragraphs 1-37 are incorporated as if set forth herein.

39. Defendants have been and are violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce, devices that are adulterated within the meaning of 21 U.S.C. § 351(h), as set forth above.

COUNT II

(21 U.S.C. § 331(a))

40. Paragraphs 1-37 are incorporated as if set forth herein.

41. Defendants have been and are violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce, devices that are adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B) and are misbranded within the meaning of 21 U.S.C. § 352(o), as set forth above.

COUNT III

(21 U.S.C. § 331(k))

42. Paragraphs 1-37 are incorporated as if set forth herein.

43. Defendants have been and are violating 21 U.S.C. § 331(k), by causing the devices to become adulterated within the meaning of 21 U.S.C. § 351(h), while such devices are held for sale after shipment in interstate commerce, as set forth above.

COUNT IV

(21 U.S.C. § 331(k))

44. Paragraphs 1-37 are incorporated as if set forth herein.

45. Defendants have been and are violating 21 U.S.C. § 331(k), by causing the devices to become adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B) and misbranded within the meaning of 21 U.S.C. § 352(o), while such devices are held for sale after shipment in interstate commerce, as set forth above.

PRAYER FOR RELIEF

WHEREFORE, the United States of America respectfully requests that this Court:

I. Permanently restrain and enjoin under 21 U.S.C. § 332(a) Defendants and each and all their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, from, directly or indirectly, manufacturing, processing, packing, holding, labeling, or distributing any device at and/or from their facility located at 1051 Olsen Street, Suite 3611, Henderson, Nevada 89011, unless and until:

A. Defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute devices are established,

operated, and administered in compliance with 21 U.S.C. § 360j(f)(1) and the Quality Management System regulation prescribed in 21 C.F.R. Part 820, and in a manner that has been found acceptable to FDA; and

B. Defendants ensure that, for each model of device designed, manufactured, and distributed, they have obtained premarket approval or clearance from FDA and that the device is designed, manufactured, and distributed in accordance with such approval or clearance;

II. Permanently restrain and enjoin under 21 U.S.C. § 332(a) Defendants and each and all their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, from directly or indirectly doing or causing the following acts:

A. Violating 21 U.S.C. § 331(a) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce, any device that is adulterated within the meaning of 21 U.S.C. §§ 351(h) or 351(f)(1)(B), or misbranded within the meaning of 21 U.S.C. § 352(o); and/or

B. Violating 21 U.S.C. § 331(k) by causing any device to become adulterated within the meaning of 21 U.S.C. §§ 351(h) or 351(f)(1)(B), or

misbranded within the meaning of 21 U.S.C. § 352(o), while such device is held for sale after shipment of one or more of its components in interstate commerce;

III. Authorize FDA pursuant to this injunction to inspect Defendants' places of business and all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any device to ensure continuing compliance with the terms of the injunction, with the costs of such inspections, including testing and sampling, to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

IV. Award the United States costs and other such relief as the Court deems just and proper.

DATED: August 6, 2026.

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