UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

FEDERAL TRADE COMMISSION,

Plaintiff,

v.

ZYCAL BIOCEUTICALS HEALTHCARE COMPANY, INC., a corporation, and

JAMES J. SCAFFIDI, individually and as an officer of ZYCAL BIOCEUTICALS HEALTHCARE COMPANY, INC.,

Defendants.

Case No. 4:20-CV-10249

[PROPOSED] STIPULATED ORDER FOR PERMANENT INJUNCTION AND OTHER RELIEF

Plaintiff, the Federal Trade Commission ("Commission" or "FTC"), filed its Complaint for Permanent Injunction and Other Equitable Relief ("Complaint"), for a permanent injunction, and other relief in this matter, pursuant to Section 13(b) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 53(b). The Commission and Defendants stipulate to the entry of this Stipulated Order for Permanent Injunction and Other Relief ("Order") to resolve all matters in dispute in this action between them.

THEREFORE, IT IS ORDERED as follows:

FINDINGS

1. This Court has jurisdiction over this matter.

2. The Complaint charges that Defendants participated in deceptive acts or practices in violation of Sections 5 and 12 of the FTC Act, 15 U.S.C. §§ 45 and 52, in the marketing and sale of one or more Cyplexinol Products.

3. Nothing in this Order alters Defendants' rights or obligations under any other statute, including the Dietary Supplement Health and Education Act, 21 U.S.C. § 343(r)(6).

4. Defendants neither admit nor deny any of the allegations in the Complaint, except as specifically stated in this Order. Only for purposes of this action, Defendants admit the facts necessary to establish jurisdiction.

5. Defendants waive any claim that they may have under the Equal Access to Justice Act, 28 U.S.C. § 2412, concerning the prosecution of this action through the date of this Order, and agree to bear their own costs and attorney fees.

6. Defendants and the Commission waive all rights to appeal or otherwise challenge or contest the validity of this Order.

DEFINITIONS

For the purpose of this Order, the following definitions apply:

A. "**Covered Product**" means any Dietary Supplement, Food, or Drug, including any Cyplexinol Product.

B. "**Cyplexinol Product**" means any Dietary Supplement, Food, or Drug containing the ingredient Cyplexinol, including Ostinol, Pro-Stiminol, and Chondrinol.

C. "**Defendants**" means the Individual Defendant and Corporate Defendant, individually, collectively, or in any combination.

1. "**Corporate Defendant**" means ZyCal Bioceuticals Healthcare Company, Inc. and its successors and assigns.

2. "**Individual Defendant**" means James J. Scaffidi.

D. "**Dietary Supplement**" means: (1) any product labeled as a dietary supplement or otherwise represented as a dietary supplement; or (2) any pill, tablet, capsule, powder, softgel, gelcap, liquid, or other similar form containing one or more ingredients that are a vitamin, mineral, herb or other botanical, amino acid, probiotic, or other dietary substance for use by humans to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any ingredient described above, that is intended to be ingested, and is not represented to be used as a conventional food or as a sole item of a meal or the diet.

E. "**Drug**" means: (1) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; (3) articles (other than food) intended to affect the structure or any function of the body of humans or other animals; and (4) articles intended for use as a component of any article specified in (1), (2), or (3); but does not include devices or their components, parts, or accessories.

F. "**Essentially Equivalent Product**" means a product that contains the identical ingredients, except for inactive ingredients (*e.g.*, binders, colors, fillers, excipients), in the same

form and dosage, and with the same route of administration (*e.g.*, orally, sublingually), as the Covered Product; *provided that* the Covered Product may contain additional ingredients if reliable scientific evidence generally accepted by experts in the field indicates that the amount and combination of additional ingredients is unlikely to impede or inhibit the effectiveness of the ingredients in the Essentially Equivalent Product.

G. "**Food**" means: (1) any article used for food or drink for humans or other animals; (2) chewing gum; and (3) any article used for components of any such article.

ORDER

I.

PROHIBITED REPRESENTATIONS REGARDING HEALTH-RELATED CLAIMS REQUIRING HUMAN CLINICAL TESTING FOR SUBSTANTIATION

IT IS ORDERED that Defendants, Defendants' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promoting, offering for sale, sale, or distribution of any Covered Product, are permanently restrained and enjoined from making, or assisting others in making, expressly or by implication, including through the use of a product or program name, endorsement, depiction, or illustration, any representation that such product:

A. Grows bone tissue or is osteoinductive;

B. Grows cartilage tissue;

C. Improves bone density or slows bone loss;

D. Cures, treats, or mitigates any orthopedic condition, including osteoarthritis, arthritis, osteoporosis, degenerative joint conditions, joint pain, and pain resulting from inflammation; or

E. Cures, mitigates, or treats any disease

unless the representation is non-misleading, and, at the time of making such representation, Defendants possess and rely upon competent and reliable scientific evidence substantiating that the representation is true.

For purposes of this Section, competent and reliable scientific evidence shall consist of human clinical testing of the Covered Product, or of an Essentially Equivalent Product, that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. Such testing must be: (1) randomized, double-blind, and placebo-controlled; and (2) conducted by researchers qualified by training and experience to conduct such testing. In addition, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing as described in the section entitled Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies must be available for inspection and production to the Commission. Persons covered by this Section have the burden of proving that a product satisfies the definition of Essentially Equivalent Product.

II.

PROHIBITED REPRESENTATIONS REGARDING OTHER HEALTH-RELATED CLAIMS

IT IS FURTHER ORDERED that Defendants, Defendants' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promoting, offering for sale, sale, or distribution of any Covered Product, are permanently restrained and enjoined from making, or assisting others in making, expressly or by implication, including through the use of a product name, endorsement, depiction, or illustration, any representation, other than representations covered under the Section of this Order entitled Prohibited Representations Regarding Health-Related Claims Requiring Human Clinical Testing For Substantiation, about the health benefits, performance, efficacy, safety, or side effects of any Covered Product, unless the representation is non-misleading, and, at the time of making such representation, they possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

For purposes of this Section, competent and reliable scientific evidence means tests, analyses, research, or studies: (1) that have been conducted and evaluated in an objective manner by experts in the relevant disease, condition, or function to which the representation relates; (2) that are generally accepted by such experts to yield accurate and reliable results; and (3) that are randomized, double-blind, and placebo-controlled human clinical testing of the Covered Product,

or of an Essentially Equivalent Product, when such experts would generally require such human clinical testing to substantiate that the representation is true. In addition, when such tests or studies are human clinical tests or studies, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing as set forth in the section entitled Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies must be available for inspection and production to the Commission. Persons covered by this Section have the burden of proving that a product satisfies the definition of Essentially Equivalent Product.

III.

PROHIBITED MISREPRESENTATIONS REGARDING TESTS, STUDIES, OR OTHER RESEARCH

IT IS FURTHER ORDERED that Defendants, Defendants' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promoting, offering for sale, sale, or distribution of any Covered Product, are permanently restrained and enjoined from misrepresenting, in any manner, or assisting others in misrepresenting, expressly or by implication, including through the use of a product name, endorsement, depiction, or illustration:

A. That any Covered Product is clinically or scientifically proven to:

1. Grow bone tissue or is osteoinductive;

2. Grow cartilage tissue;

3. Improve bone density or slow bone loss; or

4. Cure, treat, or mitigate any orthopedic condition, including osteoarthritis, arthritis, osteoporosis, degenerative joint conditions, joint pain, and pain resulting from inflammation;

B. That the performance or benefits of any product are scientifically or clinically proven or otherwise established; or

C. The existence, contents, validity, results, conclusions, or interpretations of any test, study, or other research, including by misreporting the number of study participants and their demographic information or by failing to disclose potential conflicts of interest between the study sponsors or authors and the study participants.

IV.

MEANS AND INSTRUMENTALITIES

IT IS FURTHER ORDERED that Defendants, Defendants' officers, agents, employees, attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promoting, offering for sale, sale, or distribution of any Covered Product, are permanently restrained and enjoined from providing to others the Means and Instrumentalities with which to (1) make, directly or indirectly, expressly or by implication, including through the use of endorsements or trade names, any false or misleading statement of material fact, including the representations covered by Sections I through III, above. For purposes of this Section, "Means and Instrumentalities" means any information, including any advertising, labeling, promotional, sales, training, or purported substantiation materials,

contracts, or other agreements, for use by others in their marketing or sale of any product, package, or service, in or affecting commerce.

V.

FDA-APPROVED CLAIMS

IT IS FURTHER ORDERED that nothing in this Order prohibits Defendants, Defendants' officers, agents, employees, and attorneys, or all other persons in active concert or participation with any of them from:

A. For any Drug, making a representation that is approved in labeling for such Drug under any tentative final or final monograph promulgated by the Food and Drug Administration, or under any new Drug application approved by the Food and Drug Administration; and

B. For any product, making a representation that is specifically authorized for use in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990 or permitted under Sections 303-304 of the Food and Drug Administration Modernization Act of 1997.

VI.

PRESERVATION OF RECORDS RELATING TO COMPETENT AND RELIABLE HUMAN CLINICAL TESTS OR STUDIES

IT IS FURTHER ORDERED that, with regard to any human clinical test or study ("test") upon which Defendants rely to substantiate any claim covered by this Order, Defendants shall secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of the test, including:

A. All protocols and protocol amendments, reports, articles, write-ups, or other accounts of the results of the test, and drafts of such documents reviewed by the test sponsor or any other person not employed by the research entity;

B. All documents referring or relating to recruitment; randomization; instructions, including oral instructions, to participants; and participant compliance;

C. Documents sufficient to identify all test participants, including any participants who did not complete the test, and all communications with any participants relating to the test; all raw data collected from participants enrolled in the test, including any participants who did not complete the test; source documents for such data; any data dictionaries; and any case report forms;

D. All documents referring or relating to any statistical analysis of any test data, including any pretest analysis, intent-to-treat analysis, or between-group analysis performed on any test data; and

E. All documents referring or relating to the sponsorship of the test, including all communications and contracts between any sponsor and the test's researchers.

Provided, however, the preceding preservation requirement does not apply to a reliably reported test, unless the test was conducted, controlled, or sponsored, in whole or in part by: (1) any Defendant; (2) any Defendant's officers, agents, representatives, or employees; (3) any other person or entity in active concert or participation with any Defendant; (4) any person or entity affiliated with or acting on behalf of any Defendant; (5) any supplier of any ingredient contained in the product at issue to any of the foregoing or to the product's manufacturer; or (6) the supplier or manufacturer of such product.

For purposes of this Section, "reliably reported test" means a report of the test has been published in a peer-reviewed journal, and such published report provides sufficient information about the test for experts in the relevant field to assess the reliability of the results.

For any test conducted, controlled, or sponsored, in whole or in part, by any Defendant, Defendant must establish and maintain reasonable procedures to protect the confidentiality, security, and integrity of any personal information collected from or about participants. These procedures must be documented in writing and must contain administrative, technical, and physical safeguards appropriate to the Defendant's size and complexity, the nature and scope of the Defendant's activities, and the sensitivity of the personal information collected from or about the participants.

VII.

NOTICE TO CUSTOMERS

IT IS FURTHER ORDERED that, within 30 days of the entry of this Order:

A. Corporate Defendant shall send by first-class mail or by electronic mail a notice in the exact wording and format shown in Attachment A, showing the date of the mailing or transmission, to any consumer, health professional, licensee, distributor, and wholesaler, who, as of the date of entry of this Order, is or has been a direct purchaser of Corporate Defendant's Cyplexinol Products from January 1, 2018 to the present. For consumers and health professionals, the notice will be sent to those purchasers who bought Cyplexinol Products from a ZyCal website. The subject line of the notice must state "FTC SETTLEMENT ABOUT CYPLEXINOL (OSTINOL) ADVERTISING." The notice must not contain any other message concerning Corporate Defendant's goods or services, or include any attachments.

B. For any notice sent by first-class mail, Corporate Defendant's name and return address must appear on the front of the envelope, and the customer's name and address must be printed on the front of the envelope or be visible through a window in the envelope.

C. For any notice sent by electronic mail:

1. One to three days after sending any initial notice, Corporate Defendant shall resend such notice by electronic mail in the form shown in Attachment A to those customers who did not open the initial notice.

2. Corporate Defendant must collect and maintain the following metrics on the initial and subsequent emailed notices:

a. Unique open-rate (unique opens divided by number of emails successfully delivered);

b. Click-to-open rate (unique clicks divided by the number of emails opened); and

c. Unique click rate (unique clicks divided by the number of emails successfully delivered).

3. Corporate Defendant must report to the Commission the metrics listed in this Subsection within 30 days of sending the second notice.

VIII.

ORDER ACKNOWLEDGMENTS

IT IS FURTHER ORDERED that Defendants obtain acknowledgments of receipt of this Order:

A. Each Defendant, within 7 days of entry of this Order, must submit to the Commission an acknowledgment of receipt of this Order sworn under penalty of perjury.

B. For 10 years after entry of this Order, Individual Defendant for any business that such Defendant, individually or collectively with any other Defendant, is the majority owner or controls directly or indirectly, and Corporate Defendant, must deliver a copy of this Order to: (1) all principals, officers, directors, and LLC managers and members; (2) all employees having managerial responsibilities for the manufacturing, labeling, advertising, promoting, offering for sale, sale, or distribution of any Covered Product and all agents and representatives who participate in the manufacturing, labeling, advertising, promoting, offering for sale, sale, or distribution of any Covered Product; and (3) any business entity resulting from any change in structure as set forth in the Section titled Compliance Reporting. Delivery must occur within 7 days of entry of this Order for current personnel. For all others, delivery must occur before they assume their responsibilities.

C. From each individual or entity to which a Defendant delivered a copy of this Order, that Defendant must obtain, within 30 days, a signed and dated acknowledgment of receipt of this Order.

IX.

COMPLIANCE REPORTING

IT IS FURTHER ORDERED that Defendants make timely submissions to the Commission:

A. 60 days after entry of this Order, each Defendant must submit a compliance report, sworn under penalty of perjury:

1. Each Defendant must: (a) identify the primary physical, postal, and email address and telephone number, as designated points of contact, which representatives of the Commission may use to communicate with Defendant; (b) identify all of that Defendant's businesses by all of their names, telephone numbers, and physical, postal, email, and Internet addresses; (c) describe the activities of each business, including the goods and services offered, the means of advertising, marketing, and sales, and the involvement of any other Defendant (which Individual Defendant must describe if he knows or should know due to his own involvement); (d) describe in detail whether and how that Defendant is in compliance with each Section of this Order; and (e) provide a copy of each Order Acknowledgment obtained pursuant to this Order, unless previously submitted to the Commission.

2. Additionally, Individual Defendant must: (a) identify all telephone numbers and all physical, postal, email and Internet addresses, including all residences; (b) identify all business activities, including any business for which such Defendant performs services whether as an employee or otherwise and any entity in which such Defendant has any ownership interest; and (c) describe in detail such Defendant's involvement in each such business, including title, role, responsibilities, participation, authority, control, and any ownership.

B. For 10 years after entry of this Order, each Defendant must submit a compliance notice, sworn under penalty of perjury, within 14 days of any change in the following:

1. Each Defendant must report any change in: (a) any designated point of contact; or (b) the structure of any Corporate Defendant or any entity that Defendant has any ownership interest in or controls directly or indirectly that may affect compliance obligations

arising under this Order, including: creation, merger, sale, or dissolution of the entity or any subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order.

2. Additionally, Individual Defendant must report any change in: (a) name, including aliases or fictitious name, or residence address; or (b) title or role in any business activity, including any business for which such Defendant performs services whether as an employee or otherwise and any entity in which such Defendant has any ownership interest, and identify the name, physical address, and any Internet address of the business or entity.

C. Each Defendant must submit to the Commission notice of the filing of any bankruptcy petition, insolvency proceeding, or similar proceeding by or against such Defendant within 14 days of its filing.

D. Any submission to the Commission required by this Order to be sworn under penalty of perjury must be true and accurate and comply with 28 U.S.C. § 1746, such as by concluding: "I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on: _____" and supplying the date, signatory's full name, title (if applicable), and signature.

E. Unless otherwise directed by a Commission representative in writing, all submissions to the Commission pursuant to this Order must be emailed to DEbrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: FTC v. ZyCal Bioceuticals Healthcare Co., Inc., et al. File No. X200017.

X.

RECORDKEEPING

IT IS FURTHER ORDERED that Defendants must create certain records for 10 years after entry of the Order, and retain each such record for 5 years. Specifically, Corporate Defendant and Individual Defendant for any business that such Defendant, individually or collectively with any other Defendant, owns a majority of or controls directly or indirectly, must create and retain the following records:

A. A copy of each unique advertisement or other marketing material;

B. Accounting records showing the revenues from all goods or services sold;

C. Personnel records showing, for each person providing services, whether as an employee or otherwise, that person's: name; addresses; telephone numbers; job title or position; dates of service; and (if applicable) the reason for termination;

D. Records of all consumer complaints and refund requests, whether received directly or indirectly, such as through a third party, and any response; and

E. All records necessary to demonstrate full compliance with each provision of this Order, including all submissions to the Commission.

XI.

COMPLIANCE MONITORING

IT IS FURTHER ORDERED that, for the purpose of monitoring Defendants' compliance with this Order:

A. Within 14 days of receipt of a written request from a representative of the Commission, each Defendant must: submit additional compliance reports or other requested

information, which must be sworn under penalty of perjury; appear for depositions; and produce documents for inspection and copying. The Commission is also authorized to obtain discovery, without further leave of court, using any of the procedures prescribed by Federal Rules of Civil Procedure 29, 30 (including telephonic depositions), 31, 33, 34, 36, 45, and 69.

B. For matters concerning this Order, the Commission is authorized to communicate directly with each Defendant. Defendant must permit representatives of the Commission to interview any employee or other person affiliated with any Defendant who has agreed to such an interview. The person interviewed may have counsel present.

C. The Commission may use all other lawful means, including posing, through its representatives as consumers, suppliers, or other individuals or entities, to Defendants or any individual or entity affiliated with Defendants, without the necessity of identification or prior notice. Nothing in this Order limits the Commission's lawful use of compulsory process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49, 57b-1.

D. Upon written request from a representative of the Commission, any consumer reporting agency must furnish consumer reports concerning Individual Defendant, pursuant to Section 604(1) of the Fair Credit Reporting Act, 15 U.S.C. § 1681b(a)(1).

XII.

RETENTION OF JURISDICTION

IT IS FURTHER ORDERED that this Court retains jurisdiction of this matter for purposes of construction, modification, and enforcement of this Order.

SO ORDERED this day of _____, 20__.

_____
UNITED STATES DISTRICT JUDGE

SO STIPULATED AND AGREED:

FOR PLAINTIFF FEDERAL TRADE COMMISSION:

Anisha Dasgupta
General Counsel

/s/ Mary L. Johnson Date: 02/03/2023

MARY L. JOHNSON
EDWIN RODRIGUEZ
SARAH BOTHA
KRISTIN M. WILLIAMS
Federal Trade Commission
600 Pennsylvania Avenue, N.W., Mailstop CC-6316
Washington, D.C. 20850
202-326-3115, mjohnson1@ftc.gov
202-326-3147, erodriguez@ftc.gov
202-326-2036, sbotha@ftc.gov
202-326-2619, kwilliams2@ftc.gov
202-326-3259 (facsimile)

FOR DEFENDANT ZYCAL BIOCEUTICALS HEALTHCARE CO., INC.:

_____ Date: 12/20/22

DEFENDANT JAMES J. SCAFFIDI:

_____ Date: 12/20/22

COUNSEL FOR DEFENDANTS ZYCAL BIOCEUTICALS HEALTHCARE CO., INC. AND JAMES J. SCAFFIDI:

_____

Thomas E. Gilbertsen
Paul K. Dueffert
DUEFFERT GILBERTSEN PLLC
1518 K Street N.W.
Washington, D.C. 20005
(202) 621-6516
tgilbertsen@dueffertlaw.com
pdueffert@dueffertlaw.com

Kathy Jo Cook, BBO #63138
Benjamin H. Duggan, BBO #684981
Sheff & Cook, LLC
Ten Tremont Street, 7th Floor
Boston, MA 02108
(617) 720-8447
kjcook@sheffandcook.com
bduggan@sheffandcook.com

ATTACHMENT A

[On ZyCal letterhead if mailed or with ZyCal logo if sent by email]

[On envelope if mailed or the "re" line if sent by email:]

FTC SETTLEMENT ABOUT CYPLEXINOL (OSTINOL) ADVERTISING
[content of letter or email, 16-point font]

Dear [End Users, Wholesalers, Distributors, Licensees, and Health Practitioners]:

We're writing because you bought Cyplexinol products, such as Ostinol. According to the Federal Trade Commission (FTC), ZyCal doesn't have scientific evidence to support advertising claims that Cyplexinol grows bone, grows cartilage, or relieves joint pain.

To settle the case, ZyCal has agreed to stop making these claims, unless it has adequate scientific evidence.

Learn more about the FTC's lawsuit at [URL].

Sincerely,

[ZyCal signatory]