

COMMISSIONERS: **Rebecca Kelly Slaughter, Acting Chairwoman**
 Noah Joshua Phillips
 Rohit Chopra
 Christine S. Wilson

In the Matter of

BASF SE, a corporation,

BASF CORPORATION, a corporation, and

DIEM LABS, LLC, a limited liability company,
et al.

DOCKET NO. C-4745

**DECISION AND ORDER AS TO
RESPONDENTS DIEM LABS, LLC AND
RELATED INDIVIDUALS**

DECISION

The Federal Trade Commission (“Commission”) initiated an investigation of certain acts and practices of the Respondents named in the caption. The Commission’s Bureau of Consumer Protection (“BCP”) prepared and furnished to Respondents a draft Complaint. BCP proposed to present the draft Complaint to the Commission for its consideration. If issued by the Commission, the draft Complaint would charge the Respondents with violations of the Federal Trade Commission Act.

Respondents and BCP thereafter executed an Agreement Containing Consent Order (“Consent Agreement”). The Consent Agreement includes: 1) statements by Respondents that they neither admit nor deny any of the allegations in the Complaint, except as specifically stated in this Decision and Order, and that only for purposes of this action, they admit the facts necessary to establish jurisdiction; and 2) waivers and other provisions as required by the Commission’s Rules.

The Commission considered the matter and determined that it had reason to believe that Respondents have violated the Federal Trade Commission Act, and that a Complaint should issue stating its charges in that respect. The Commission accepted the executed Consent Agreement and placed it on the public record for a period of 30 days for the receipt and consideration of public comments. The Commission duly considered any comments received from interested persons pursuant to Section 2.34 of its Rules, 16 C.F.R. § 2.34. Now, in further conformity with the procedure prescribed in Rule 2.34, the Commission issues its Complaint, makes the following Findings, and issues the following Order:

Findings

1. The Proposed Respondents are:
 - a. DIEM Labs, LLC, (“DIEM”) a Michigan limited liability company, with its principal office or place of business at 221 Dino Dr., Ann Arbor, MI 48103-9123.
 - b. Cai Berg, an officer of DIEM. Individually or in concert with others, he formulates, directs, or controls the policies, acts, or practices of DIEM. His principal office or place of business is the same as that of DIEM.
 - c. Tim Prince, an officer of DIEM Labs, LLC. Individually or in concert with others, he formulates, directs, or controls the policies, acts, or practices of DIEM Labs, LLC. His principal office or place of business is the same as that of DIEM.
2. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondents, and the proceeding is in the public interest.

ORDER

Definitions

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

- A. “**Covered Product**” means Hepaxa, Hepaxa PD, and any other Dietary Supplement, Food, or Drug that contains one or more Omega-3 fatty acids or is promoted by a Respondent or its subsidiary to benefit cardiac, metabolic, or hepatic health or functions, including the prevention, mitigation, treatment, or cure of any disease of such systems.
- B. “**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.
- C. “**Drug**” means: (1) articles recognized in the official United States Pharmacopoeia, official Homoeopathic 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; (3) articles (other than Food) intended to affect the structure or any function of the body of humans; 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.

- D. “**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.
- E. “**Food**” means: (1) any article used for Food or drink for humans; (2) chewing gum; and (3) any article used for components of any such article.
- F. “**Respondents**” means means all of the Individual Respondents and the Corporate Respondents, individually, collectively, or in any combination.
1. “**Corporate Respondents**” means DIEM Labs, LLC, and its successors and assigns, including DIEM Direct, LLC.
 2. “**Individual Respondents**” means Cai Berg and Tim Prince.

Provisions

I. Prohibited Representations: Regarding Health-Related Claims Requiring Human Clinical Testing for Substantiation

IT IS ORDERED that Respondents, Respondents’ 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 labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, must not make, expressly or by implication, including through the use of a product or program name, endorsement, depiction, or illustration, any representation that such product reduces liver fat in adults or children with Non-alcoholic Fatty Liver Disease (NAFLD), or cures, mitigates, or treats any disease, including but not limited to liver disease, unless the representation is non-misleading, and, at the time of making such representation, they possess and rely upon competent and reliable scientific evidence substantiating that the representation is true. For purposes of this Provision, competent and reliable scientific evidence must 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 Provision 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 Provision have the burden of proving that a product satisfies the definition of Essentially Equivalent Product.

II. Prohibited Claims: Other Health-Related Claims

IT IS FURTHER ORDERED that Respondents, Respondents' 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 labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, must not make, expressly or by implication, including through the use of a product or program name, endorsement, depiction, or illustration, any representation, other than representations covered under the Provision 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 Provision, 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 Provision 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 Provision 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 Respondents, Respondents' 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 labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, must not misrepresent, in any manner, expressly or by implication, including through the use of any product or program name, endorsement, depiction, or illustration:

- A. that any Covered Product is clinically proven to reduce liver fat in adults or children with NAFLD;

- B. that any Covered Product is clinically proven to cure, mitigate, or treat any disease;
- C. that the health benefits, performance, or safety of any Covered Product is scientifically or clinically proven or otherwise established; or
- D. the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research relating to the health benefits, performance, safety, or side effects of any Covered Product.

IV. FDA-Approved Claims

IT IS FURTHER ORDERED that nothing in this Order prohibits Respondents, Respondents' 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.

V. 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 Respondents rely to substantiate any claim covered by this Order, Respondents must 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) the Respondent; (2) the Respondent's officers, agents, representatives, or employees; (3) any other person or entity in active concert or participation with the Respondent; (4) any person or entity affiliated with or acting on behalf of the Respondent; (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 Provision, "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 the Respondent, the Respondent 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 Respondent's size and complexity, the nature and scope of the Respondent's activities, and the sensitivity of the personal information collected from or about the participants.

VI. Monetary Relief

IT IS FURTHER ORDERED that:

- A. Respondents must pay to the Commission \$157,318, which Respondents stipulate their counsel, Kane Kessler, P.C., holds in escrow for no purpose other than payment to the Commission.
- B. Such payment must be made within 8 days of the effective date of this Order by electronic fund transfer in accordance with instructions provided by a representative of the Commission.

VII. Additional Monetary Provisions

IT IS FURTHER ORDERED that:

- A. Respondents relinquish dominion and all legal and equitable right, title, and interest in all assets transferred pursuant to this Order and may not seek the return of any assets.

- B. The facts alleged in the Complaint will be taken as true, without further proof, in any subsequent civil litigation by or on behalf of the Commission, including in a proceeding to enforce its rights to any payment or monetary judgment pursuant to this Order, such as a nondischargeability complaint in any bankruptcy case.
- C. The facts alleged in the Complaint establish all elements necessary to sustain an action by the Commission pursuant to Section 523(a)(2)(A) of the Bankruptcy Code, 11 U.S.C. § 523(a)(2)(A), and this Order will have collateral estoppel effect for such purposes.
- D. All money paid to the Commission pursuant to this Order may be deposited into a fund administered by the Commission or its designee to be used for relief, including consumer redress and any attendant expenses for the administration of any redress fund. If a representative of the Commission decides that direct redress to consumers is wholly or partially impracticable or money remains after redress is completed, the Commission may apply any remaining money for such other relief (including consumer information remedies) as it determines to be reasonably related to Respondent's practices alleged in the Complaint. Any money not used is to be deposited to the U.S. Treasury. Respondent has no right to challenge any activities pursuant to this Provision.
- E. In the event of default on any obligation to make payment under this Order, interest, computed as if pursuant to 28 U.S.C. § 1961(a), shall accrue from the date of default to the date of payment. In the event such default continues for 10 days beyond the date that payment is due, the entire amount will immediately become due and payable.
- F. Each day of nonpayment is a violation through continuing failure to obey or neglect to obey a final order of the Commission and thus will be deemed a separate offense and violation for which a civil penalty shall accrue.
- G. Respondents acknowledge that their Taxpayer Identification Numbers (Social Security or Employer Identification Numbers), which Respondents have previously submitted to the Commission, may be used for collecting and reporting on any delinquent amount arising out of this Order, in accordance with 31 U.S.C. § 7701.

VIII. Customer Information

IT IS FURTHER ORDERED that Respondents, Respondents' officers, agents, employees, and attorneys, or all other persons in active concert or participation with any of them, must directly or indirectly provide sufficient customer information, including sufficient identification of all resellers, to enable the Commission to efficiently administer consumer redress to purchasers of Hepaxa and Hepaxa PD. If a representative of the Commission requests in writing any information related to redress, Respondents must provide it, in the form prescribed by the Commission, within 14 days.

IX. Acknowledgments of the Order

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

- A. Each Respondent, within 10 days after the effective date of this Order, must submit to the Commission an acknowledgment of receipt of this Order.
- B. Each Individual Respondent for any business that such Respondent, individually or collectively with any other Respondents, is the majority owner or controls directly or indirectly, and each Corporate Respondent, must deliver a copy of this Order to: (1) all principals, officers, directors, and LLC managers and members; (2) all employees, agents, and representatives with managerial responsibilities for conduct related to the subject matter of the Order; and (3) any business entity resulting from any change in structure as set forth in the Provision titled Compliance Reports and Notices. Delivery must occur within 10 days after the effective date 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 Respondent delivered a copy of this Order, that Respondent must obtain, within 30 days, a signed and dated acknowledgment of receipt of this Order.

X. Compliance Reports and Notices

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

- A. One year after the issuance date of this Order, each Respondent must submit a compliance report, sworn under penalty of perjury, in which:
 1. Each Respondent 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 Respondent; (b) identify all of that Respondent'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 Respondent (which Individual Respondents must describe if they know or should know due to their own involvement); (d) describe in detail whether and how that Respondent is in compliance with each Provision of this Order, including a discussion of all of the changes the Respondent made to comply with the Order; and (e) provide a copy of each Acknowledgment of the Order obtained pursuant to this Order, unless previously submitted to the Commission.

2. Additionally, each Individual Respondent must: (a) identify all his or her telephone numbers and all his or her physical, postal, email and Internet addresses, including all residences; (b) identify all his or her business activities, including any business for which such Respondent performs services whether as an employee or otherwise and any entity in which such Respondent has any ownership interest; and (c) describe in detail such Respondent's involvement in each such business activity, including title, role, responsibilities, participation, authority, control, and any ownership.
- B. For a period of 10 years after the issuance date of the Order, each Respondent must submit a compliance notice, sworn under penalty of perjury, within 14 days of any change in the following:
1. Each Respondent must submit notice of any change in: (a) any designated point of contact; or (b) the structure of any Corporate Respondent or any entity that Respondent 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, each Individual Respondent must submit notice of any change in: (a) name, including alias or fictitious name, or residence address; or (b) title or role in any business activity that may affect compliance obligations under the order, including (i) any business for which such Respondent performs services whether as an employee or otherwise, and (ii) any entity in which such Respondent has any ownership interest and over which Respondents have direct or indirect control. For each such business activity, also identify its name, physical address, and any Internet address.
- C. Each Respondent must submit notice of the filing of any bankruptcy petition, insolvency proceeding, or similar proceeding by or against such Respondent 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: In re DIEM Labs, LLC.

XI. Recordkeeping

IT IS FURTHER ORDERED that Respondents must create certain records for 10 years after the issuance date of the Order, and retain each such record for 5 years. Specifically, Corporate Respondent and each Individual Respondent for any business relating to a Covered Product that such Respondent, individually or collectively with any other Respondents, is a majority owner or controls directly or indirectly, must create and retain the following records:

- A. accounting records showing the revenues from such products;
- B. personnel records showing, for each person providing services in relation to any aspect of the Order, 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;
- C. records of all consumer complaints concerning the subject matter of the order and all refund requests, whether received directly or indirectly, such as through a third party, and any response;
- D. all records necessary to demonstrate full compliance with each provision of this Order, including all submissions to the Commission;
- E. a copy of each unique advertisement or other marketing material making a representation subject to this Order;
- F. for 5 years from the date of the last dissemination of any representation covered by this Order:
 - 1. all materials that were relied upon in making the representation; and
 - 2. all tests, studies, analysis, demonstrations, other research or other such evidence in Respondent's possession, custody, or control that contradicts, qualifies, or otherwise calls into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.
- G. for 5 years from the date received, copies of all subpoenas and other communications with law enforcement, if such communication relate to Respondents' compliance with this Order.
- H. for 5 years from the date created or received, all records, whether prepared by or on behalf of Respondents, that demonstrate non-compliance or tend to show any lack of compliance by Respondents with this Order.

XII. Compliance Monitoring

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

- A. Within 10 days of receipt of a written request from a representative of the Commission, each Respondent 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 Respondent. Respondents must permit representatives of the Commission to interview any employee or other person affiliated with Respondent 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 Respondents or any individual or entity affiliated with Respondents, 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 Respondents, pursuant to Section 604(2) of the Fair Credit Reporting Act, 15 U.S.C. § 1681b(a)(2).

XIII. Order Effective Dates

IT IS FURTHER ORDERED that this Order is final and effective upon the date of its publication on the Commission's website (ftc.gov) as a final order. This Order will terminate 20 years from the date of its issuance (which date may be stated at the end of this Order, near the Commission's seal), or 20 years from the most recent date that the United States or the Commission files a complaint (with or without an accompanying settlement) in federal court alleging any violation of this Order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

- A. Any Provision in this Order that terminates in less than 20 years;
- B. This Order's application to any Respondent that is not named as a defendant in such complaint; and
- C. This Order if such complaint is filed after the Order has terminated pursuant to this

Provision.

Provided, further, that if such complaint is dismissed or a federal court rules that the Respondent did not violate any provision of the Order, and the dismissal or ruling is either not appealed or upheld on appeal, then the Order will terminate according to this Provision as though the complaint had never been filed, except that the Order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

April J. Tabor
Secretary

SEAL:
ISSUED: May 25, 2021