

## Complaint

## IN THE MATTER OF

**BASF SE,  
BASF CORPORATION,  
AND  
DIEM LABS, LLC**

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTIONS 5 AND 12 OF THE  
FEDERAL TRADE COMMISSION ACT

*Docket No. C-4745; File No. 192 3088  
Complaint, May 24, 2021 – Decision, May 24, 2021*

This consent order addresses DIEM Labs, LLC's advertising for Hepaxa and Hepaxa PD capsules containing omega-3 fatty acids. The complaint alleges that respondent violated Sections 5 and 12 of the FTC Act by representing that Hepaxa reduces liver fat in most adults with Non-alcoholic Fatty Liver Disease ("NAFLD") within six months, that Hepaxa PD reduces liver fat in most children with NAFLD within six months, that tests prove that Hepaxa reduces liver fat in adults with NAFLD and that tests prove that Hepaxa PD reduces liver fat in children with NAFLD. The consent order prohibits any representation that 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, reduces liver fat in adults or children with NAFLD, or cures, mitigates, or treats any disease, including but not limited to liver disease, unless the representation is non-misleading, including that, at the time such representation is made, they possess and rely upon competent and reliable scientific evidence that substantiates that the representation is true.

*Participants*

For the *Commission*: Janet Evans and Keith Fentonmiller.

For the *Respondents*: Willard K. Tom, Morgan Lewis and Bockius; Jeffrey H. Daichman, Kane Kessler P.C.

**COMPLAINT**

The Federal Trade Commission, having reason to believe that BASF SE, a corporation, BASF Corporation, a corporation, DIEM Labs, LLC, a limited liability company, Cai Berg, individually and as President and CEO of DIEM Labs, LLC, and Tim Prince, individually and as an officer of DIEM Labs, LLC (collectively, "Respondents"), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent BASF SE ("BASF") is a multi-national corporation based in Ludwigshafen, Germany. BASF is the publicly-traded parent company of the BASF Group, which has subsidiaries and joint ventures in more than 90 countries, including the United States. Through its Nutrition & Health division, BASF develops, produces, and markets dietary supplements, medical foods, aroma additives, and animal nutrition ingredients in Europe, North America, South America and in the Asia-Pacific region. BASF AS is BASF's main operating

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company in Norway and serves as the head of BASF's omega-3 business. BASF developed the omega-3 fish oil supplements Hepaxa and Hepaxa PD for the North American market to treat Non-Alcoholic Fatty Liver Disease ("NAFLD"). NAFLD, also called hepatic steatosis or fatty liver disease, is an excessive build-up of fat in the liver from causes other than alcohol use, such as obesity, diabetes, or high cholesterol. BASF sponsored human clinical testing of Hepaxa in the United States, prepared articles about the benefits of Hepaxa and Hepaxa PD for persons with NAFLD, posted the articles on Hepaxa-USA.com, and promoted Hepaxa research at the 2018 American Association for the Study of Liver Diseases conference in San Francisco, California. BASF supplies Hepaxa products to DIEM Labs, LLC ("DIEM"), the exclusive distributor for the U.S. market. BASF also reviews and approves all Hepaxa-related marketing and advertising materials prepared by DIEM for the U.S. market, including content on Hepaxa-USA.com.

2. Respondent BASF Corporation ("BASF US") is a Delaware corporation with offices at 100 Park Avenue, Florham Park, New Jersey 07932. BASF US is BASF's largest subsidiary and operates as BASF's North American headquarters. BASF US retained DIEM to serve as the sole U.S. distributor of Hepaxa and Hepaxa PD and issued a press release regarding Hepaxa and Hepaxa PD's benefits.

3. Respondent DIEM is a Michigan limited liability company, with its principal office or place of business at 221 Dino Dr., Ann Arbor, MI 48103-9123. DIEM serves as BASF's sole distributor of Hepaxa and Hepaxa PD in the United States, and engages in marketing activities for the products.

4. Individual Respondent Cai Berg is DIEM's President and CEO. He is also 50% owner of the corporation that owns 99% of DIEM. He is primarily responsible for DIEM's operations, contracting, human resources, finances, and product development. He was copied on all correspondence relating to the clinical trial conducted on Hepaxa, including correspondence relating to the fact that the trial failed to demonstrate that Hepaxa reduced fatty liver, and he engaged in communication with BASF regarding the results of the study. He also reviewed and approved DIEM's advertising for Hepaxa and promoted the product at medical conferences. At all times material to this Complaint, acting alone or in concert with others, he formulated, directed, controlled, had the authority to control, or participated in the acts and practices of DIEM set forth in this Complaint. His principal office or place of business is 221 Dino Dr., Ann Arbor, MI 48103-9123.

5. Individual Respondent Timothy Prince is DIEM's Director of Sales. He was provided with access to the raw data from the Hepaxa clinical study and made suggestions for alternative analyses of the data in an effort to find a successful sales pitch for the product. Thereafter, he participated in preparing deceptive advertising for Hepaxa and trained the Hepaxa sales force. He personally promoted Hepaxa as an effective treatment for NAFLD at various medical conferences. Individually or in concert with others, he controlled or had the authority to control and participated in the acts and practices of DIEM, including the acts and practices alleged in this complaint. His principal office or place of business is 221 Dino Dr., Ann Arbor, MI 48103-9123.

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6. Respondents advertise, label, promote, offer for sale, sell, and distribute Hepaxa and Hepaxa PD, products containing omega-3 long-chain polyunsaturated fatty acids (abbreviated as “omega-3 PUFAs” or “n-3 PUFAs”) sourced from fish oil. Respondents sell 120-capsule bottles of Hepaxa to treat adults with NAFLD. The product label recommends a daily dose of four capsules. Respondents also offer 120-capsule bottles of Hepaxa PD to treat children ages ten to eighteen with NAFLD. Hepaxa PD’s product label recommends a daily dosage of one to two capsules, depending on the child’s body weight. Each Hepaxa and Hepaxa PD capsule contains 675 mg of omega-3 fatty acids, consisting of at least 320 mg eicosapentaenoic acid (“EPA”) and 260 mg docosahexaenoic acid (“DHA”). Consumers can purchase a bottle of Hepaxa or Hepaxa PD for \$48 by calling a 1-800 number, sending a fax, or by ordering online at [www.Hepaxa-USA.com](http://www.Hepaxa-USA.com). Hepaxa and Hepaxa PD are “drugs” within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.

7. The acts and practices of Respondents alleged in this complaint have been in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act.

8. Respondents have disseminated or caused to be disseminated advertisements and promotional materials for Hepaxa and Hepaxa PD through the Hepaxa-USA.com website, Google AdWords that directed consumers to Hepaxa-USA.com, banner advertisements on Medscape and WebMD, press releases, and posts on Twitter and LinkedIn. These materials contain the following statements and depictions, among others:

- a. [Hepaxa-USA.com Landing Page](http://Hepaxa-USA.com) (originally posted October 2018)



\* \* \*

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- b. Hepaxa-USA.com Pages Specific to Hepaxa (posted Oct. 2018-Dec. 2019)

# CUT THE LIVER FAT

Hepaxa® is designed for management of Non-Alcoholic Fatty Liver Disease

\* \* \*

Most adult NAFLD patients will experience benefit after six months of daily supplementation with Hepaxa®.



\* \* \*

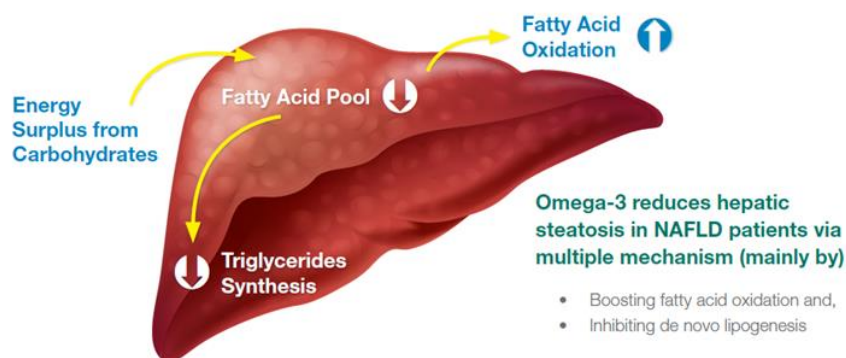
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## Hepaxa™ decreases Fatty Acid storage in the liver

▶ Hepaxa® is a highly purified, pharmaceutical-grade Omega-3 PUFA concentrate clinically demonstrated to reduce fatty acid storage in the liver.

\* \* \*

The high-purity, highly concentrated Omega-3 in Hepaxa® cannot be found in any other Omega-3 product. Do not attempt to substitute with over-the-counter fish oil, as these products are not the same as Hepaxa® and may contain substances that interfere with your healthcare objectives.



c. [Hepaxa-USA.com](http://Hepaxa-USA.com) Pages Specific to Hepaxa PD (available online Oct. 2018-Dec. 2019)

## CUT THE LIVER FAT

Hepaxa®PD is designed for management of Pediatric Non-Alcoholic Fatty Liver Disease

\* \* \*

Most pediatric NAFLD patients will experience benefits after six months of daily supplementation with Hepaxa®PD.



## Complaint

- d. Hepaxa-USA.com Pages Regarding Clinical Evidence (available online Oct. 2018-Dec. 2019)

### Clinical Trial (RCT) on Hepaxa®.

A randomized placebo-controlled clinical trial using Hepaxa® was published in NUTRIENTS (Aug, 2018). The link to the online article is provided as: <http://www.mdpi.com/2072-6643/10/8/1126/htm>

- \* Identification of patient most likely to respond – early-stage NAFLD patients with an FLI score > 40 had a clear response to Hepaxa®. On average, the HFF of these patients dropped from 20% to 10%.
- \* Confirmation of an effective threshold dose for EPA/DHA as Hepaxa® was effective in lowering steatosis in NAFLD patients.

### Meta Analysis on Omega-3 Supplementation for NAFLD.

A 2018 meta analysis summarized the results of various clinical studies over the past decade to confirm:

- The ideal NAFLD patient to be those with early-stage steatosis (rather than later stage NASH)
- The effective therapeutic daily dose threshold is 3gr omega-3 or 2.5gr of EPA/DHA

### Multiple studies utilizing PUFA for dietary management of NAFLD

## Complaint

## Hepaxa® | Clinical Evidence

| STUDY                | SIZE  | DURATION  | Liver Fat Reduction vs. Placebo | Liver Enzyme Reduction vs. Placebo | Lipid Levels Improvement vs. Placebo |
|----------------------|-------|-----------|---------------------------------|------------------------------------|--------------------------------------|
| Capanni et al., 2006 | N=56  | 12 months | ✓                               | ✓                                  | ✓                                    |
| Chen et al., 2008    | N=46  | 6 months  | ✓                               | ✓                                  | ✓                                    |
| Cussons et al., 2009 | N=25  | 2 months  | ✓                               | NS                                 | ✓                                    |
| Li et al., 2015      | N=78  | 6 months  | ✓                               | ✓                                  | ✓                                    |
| Sofi et al., 2010    | N=11  | 12 months | ✓                               | ✓                                  | ✓                                    |
| Spadaro et al., 2008 | N=36  | 6 months  | ✓                               | ✓                                  | ✓                                    |
| Zhu et al., 2008     | N=144 | 6 months  | ✓                               | ✓                                  | ✓                                    |

[Click for white paper on Adult NAFLD Management](#)

**In an RCT, DHA supplementation decreases liver fat and visceral fat, and ameliorates metabolic abnormalities in children with NAFLD. <sup>a</sup>**

**In an RCT, DHA supplementation improves liver steatosis in children with NAFLD. <sup>b</sup>**

**In an RCT, DHA supplementation in children decreased the rate of steatosis, elevated ALT and elevated AST in the 12-month treatment in the PUFA group. <sup>c</sup>**

## Multiple studies utilizing PUFA for dietary management of Pediatric NAFLD

| STUDY                      | STUDY SIZE | STUDY DURATION | Improvement of Liver Fat | Reduction in Liver Enzymes | Change in Insulin/Insulin Resistance | Decrease in Triglycerides |
|----------------------------|------------|----------------|--------------------------|----------------------------|--------------------------------------|---------------------------|
| Nobili V et al, 2011, 2013 | N=60       | 24 months      | ✓                        | ✓                          | ✓                                    | ✓                         |
| Pacifico L et al, 2015     | N=58       | 6 months       | ✓                        | ✓                          | ✓                                    | ✓                         |
| Boyraz M et al., 2015      | N=108      | 12 months      | ✓                        | ✓                          | ✓                                    | ✓                         |
| Janczyk et al., 2015       | N=64       | 6 months       | NS                       | ✓                          | NS                                   | NS                        |

[Click for white paper on Pediatric NAFLD Management](#)

\* \* \*

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**Pediatric NAFLD can be reversed.**

If NAFLD is addressed early, with adjustment to diet and exercise, many children can naturally reverse their liver fat composition to less than 5%. Doing so can restore their natural liver function and help to improve their overall and long-term health.

However, many children with NAFLD patients have been unsuccessful in making lifestyle changes to the extent needed for better health. In these cases, doctors want to provide extra help. Clinical studies have shown that daily use of poly unsaturated fatty acids (PUFA) like Hepaxa®PD can reduce liver fat and in time reverse steatosis in NAFLD. Hepaxa®PD is designed to help the dietary management of steatosis in children with early stage NAFLD.

\* \* \*

**Clinical Evidence for management of Pediatric NAFLD with (PUFA) Hepaxa®PD****Clinical Support (6-24 months)**

In a double-blind, placebo controlled trial, DHA supplementation decreases liver and visceral fat, and ameliorates metabolic abnormalities in children with NAFLD.<sup>3</sup>



**DHA SIGNIFICANTLY  
DECREASES** the  
MRI-determined liver fat  
content independently of  
BMI-SDS changes in  
6 months.  
(Average age 10.8)

\* \* \*

In a randomized controlled trial, DHA supplementation improves liver steatosis in children with NAFLD.<sup>1</sup>

| Groups     | Cleared of Fatty Liver | Reverting to Degree 1 | Probability of Moderate Steatosis | Probability of Degree 3  |
|------------|------------------------|-----------------------|-----------------------------------|--------------------------|
| DHA Groups | 10-15%                 | 40-50%                | 25-35%                            | Reduced from 60% to <10% |
| Placebo    | 0%                     | 20%                   | 45%                               | Reduced from 60% to 40%  |

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- e. BASF Press Release (posted February 22, 2018 at [www.basf.com/global/en/media/news-releases/2018/02/p-18-130.html](http://www.basf.com/global/en/media/news-releases/2018/02/p-18-130.html))

## BASF launches Hepaxa as first dedicated product in the U.S. to help patients manage Non-Alcoholic Fatty Liver Disease

FLORHAM PARK, NJ, and ANN ARBOR, MI, February 22, 2018 – BASF Corporation is introducing [Hepaxa™](#), a product that can help tens of millions of patients manage Non-Alcoholic Fatty Liver Disease (NAFLD), one of the most common forms of chronic liver disease. Providing highly concentrated and pure eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), Hepaxa is the first product in the U.S. specifically designed to address a buildup of fat in the liver, known as steatosis, in NAFLD patients. Hepaxa will be distributed nationally through [DIEM Labs, LLC](#).

Studies have shown that NAFLD patients are deficient in EPA and DHA. Hepaxa increases the levels of these important fatty acids in the blood, which improves the liver's ability to process excessive fat stored there while inhibiting the conversion of dietary carbohydrates into fat.

A 2017 BASF study has shown that Hepaxa is effective and safe in the dietary management of NAFLD patients. BASF plans to publish the clinical results of this product-specific human intervention trial in the second half of 2018.

Hepaxa is manufactured using a patented purification technology removing persistent organic pollutants and other unwanted lipids such as cholesterol, which are naturally found in all fish oil-based products. Research has shown that one specific pollutant, PCB 153, is particularly harmful to NAFLD patients. The liver function of NAFLD patients is compromised and it is important to avoid additional exposure to unwanted components of traditional fish oil.

"BASF's launch of Hepaxa is the result of our research and development efforts targeting liver health, where we are capitalizing on our unique scientific competencies," says Christoph Garbotz, Head of Commercial Management Advanced Health Solutions, BASF. "With NAFLD rapidly becoming a major public health concern worldwide, we are proud to now offer this first-to-market, dedicated solution for NAFLD patients in the U.S."

"Hepaxa is uniquely positioned to support the dietary management of steatosis in NAFLD patients," says Tim Prince, Director of Sales at DIEM Labs. "Healthcare providers are continuously looking for an adjunctive treatment to exercise and weight loss therapy to recommend to their patients. Hepaxa can now be used to begin turning around NAFLD in as little as six months."

Hepaxa is available as a medical food product in the U.S. to NAFLD patients 10 years and older for use under physician supervision. Physicians and healthcare professionals may request clinical support literature and product samples, and patients can gather information to share with their physicians, at [www.Hepaxa-USA.com](http://www.Hepaxa-USA.com).



Tony Graetzer

+1-201-704-2670

[Send email](#)

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- f. BASF Press Release (posted Oct. 29, 2018 at [www.basf.com/global/en/media/news-releases/2018/10/p-18-356.html](http://www.basf.com/global/en/media/news-releases/2018/10/p-18-356.html))



## News Release

29 October 2018

### **BASF clinical trial reveals significant reduction in liver fat content in patients with non-alcoholic fatty liver disease**

Oslo, Norway – October 29, 2018 – BASF AS completed a randomized, placebo-controlled clinical trial in the U.S., newly published in [Nutrients](#), evaluating the use of high concentrate omega-3 to correct the nutritional deficiency of omega-3 fatty acid in patients with non-alcoholic fatty liver disease (NAFLD). Several studies have shown that NAFLD patients have lower levels of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA)<sup>i</sup>.

The study, covering 176 patients, demonstrates that intervention with high concentrate omega-3 for 24 weeks significantly raises the omega-3 index in adults with NAFLD compared to placebo, thereby correcting the patients' nutritional deficiency. Patients showed reductions of up to 44% in liver fat after placebo correction, providing evidence that clinical management of NAFLD with high concentrate omega-3 has a beneficial outcome on liver fat. This intervention study supports a recently published [meta-analysis](#) that concluded that omega-3 fatty acids are associated with significant improvements in liver fat and liver function tests with approximately 3g of EPA and DHA daily.

"Science has always been the backbone of all our development work and efforts in the area of liver health, and this study is further evidence that Hepaxa can significantly reduce liver fat content, which is crucial in managing NAFLD." says Derek Tobin, Team Leader for Innovation, Advanced Health Solutions, BASF.

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g. LinkedIn Posts

**Christoph Garbotz** • 3rd+  
Head of Adaptive Business Networks  
1 yr •

Results of BASF's latest research in Non-Alcoholic Fatty Liver Disease were published today!

More to be presented in 2 weeks at [#AASLD2018](#) in San Francisco. See you there

**BASF**  
1,166,794 followers  
1 yr •

[+ Follow](#)

BASF completed a randomized, placebo-controlled clinical trial in the U.S., evaluating the use of high concentrate omega-3 to correct the nutritional deficiency of omega-3 fatty acid in patients with non-alcoholic fatty liver disease (NAFLD).  
The study demonstrates that intervention with high concentrate omega-3 for 24 weeks significantly raises the omega-3 index in adults with NAFLD compared to placebo, thereby correcting the patients' nutritional deficiency.



**BASF clinical trial reveals significant reduction in liver fat content in patients with non-alcoholic fatty liver disease**  
basf.com

13 • 2 Comments

Like Comment Share

**Christoph Garbotz** • 3rd+  
Head of Adaptive Business Networks  
1 yr •

Exciting new research that has just been published! Further evidence that increasing the intake of Omega-3 Lon Chain-PUFAs can help with the dietary management of NAFLD.

**BASF**  
1,166,795 followers  
1 yr •

[+ Follow](#)

Benefits of omega-3 long-chain fatty acids (n-3 LC-PUFAs) in patients with non-alcoholic fatty liver disease revealed in meta-analysis of 18 studies published by Nutrition Reviews®. The dietary management with n-3 LC-PUFAs resulted in statistically significant improvements in liver fat content, steatosis score, and several cardiometabolic risk factors.



**Benefits of omega-3 long-chain fatty acids in patients with non-alcoholic fatty liver disease revealed in meta-analysis of 18 studies**  
basf.com

20 • 1 Comment

Like Comment Share

h. Twitter Post

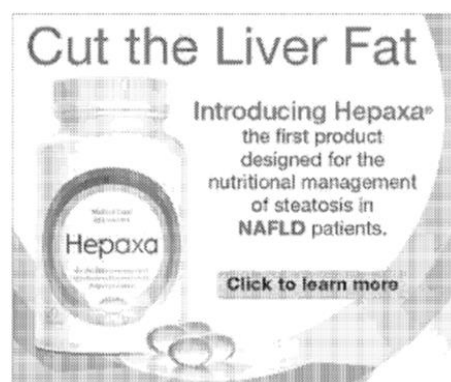
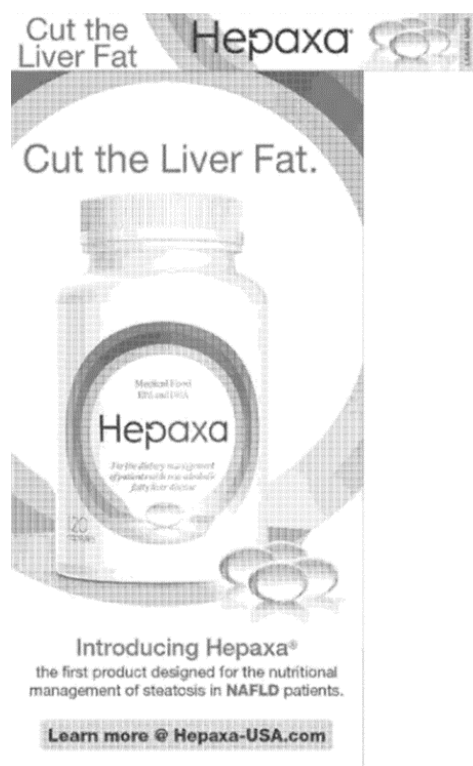
**BASF Human Nutrition** ✓ @BASF\_nutrition · Oct 29, 2018

BASF's latest clinical trial published in [@Nutrients\\_MDPI](#) showed significant reduction in liver fat in patients with NAFLD! Read about the use of high concentrate omega-3 to correct the nutritional deficiency of omega-3 fatty acid in patients with NAFLD. [in.basf.com/42vxvyw](https://in.basf.com/42vxvyw)



3 Retweets 8 Likes

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i. Online Banner Ads

9. The clinical trial referred to in Paragraphs 10.E, 10.F, and 10.G. was published as Derek Tobin, et al., Evaluation of a High Concentrate Omega-3 for Correcting the Omega-3 Fatty Acid Nutritional Deficiency in Non-Alcoholic Fatty Liver Disease (CONDIN), 10 Nutrients 1126 (2018). The CONDIN study was a randomized, double-blind human clinical trial designed to evaluate whether Hepaxa raises levels of omega-3 PUFAs in red blood cells and reduces liver fat in adults with NAFLD. For six months, 81 subjects in the treatment arm received Hepaxa and 86 in the control arm took an olive oil placebo. All study participants were advised to reduce calorie intake and to maintain stable physical activity levels. Liver fat was measured using Magnetic Resonance Imaging in 120 subjects, 60 in each arm. At the end of the study, the MRI data showed no statistically significant reduction in liver fat in the Hepaxa patients, as compared to the placebo patients.

10. Due to the CONDIN study's failure to show an effect on liver fat, BASF, DIEM, and the researchers subjected the data to "post hoc" analyses of different subgroups of test subjects, in an attempt to find a positive selling message. A post hoc analysis is a statistical analysis conducted after the data have been collected in hopes of discovering statistical relationships that suggest cause and effect. Unplanned, post hoc subgroup analyses pose a high risk of generating spurious findings and need to be confirmed by further studies. Therefore, post hoc analyses yield results that are exploratory, at best.

11. BASF and DIEM settled on a post hoc analysis that stratified patients by their baseline Fatty Liver Index ("FLI") score. The FLI score derives from an algorithm combining

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waist circumference and body mass index with blood serum levels of triglycerides and a specific liver enzyme. The post hoc analysis found that a small subgroup of patients with a baseline FLI over 40 experienced a statistically significant reduction in liver fat after using Hepaxa, as compared to placebo; however, this subgroup included only five Hepaxa patients and twelve placebo patients.

12. Other than the CONDIN study, Respondents have not conducted a human clinical trial on Hepaxa's effect on liver fat. Respondents have not tested Hepaxa PD on children at all. Moreover, there are no competent and reliable human clinical trials of products that are the same as Hepaxa. Other liver fat studies on which Respondents rely tested omega-3 PUFAs from a variety of sources, many of which contained significantly different amounts of DHA or EPA, and/or included omega-3 PUFAs not found in Hepaxa or Hepaxa PD.

### **Count I False or Unsubstantiated Efficacy Claims**

13. In connection with the advertising, promotion, offering for sale, or sale of Hepaxa and Hepaxa PD, Respondents have represented, directly or indirectly, expressly or by implication, that:

- a. Hepaxa reduces liver fat in most adults with NAFLD within six months; and
- b. Hepaxa PD reduces liver fat in most children with NAFLD within six months.

14. The representations set forth in Paragraph 13 are false or misleading or were not substantiated at the time the representations were made.

### **Count II False Establishment Claim**

15. In connection with the advertising, marketing, promotion, offering for sale, or sale of Hepaxa and Hepaxa PD, including through the means described in Paragraph 10, Respondents have represented, directly or indirectly, expressly or by implication, that:

- a. Tests prove that Hepaxa reduces liver fat in adults with NAFLD; and
- b. Tests prove that Hepaxa PD reduces liver fat in children with NAFLD.

16. In fact:

- a. Tests do not prove that Hepaxa reduces liver fat in adults with NAFLD; and
- b. Tests do not prove that Hepaxa PD reduces liver fat in children with NAFLD.

17. Therefore, the representations set forth in Paragraph 17 are false or misleading.

## Decision and Order

**Violations of Sections 5 and 12**

18. The acts and practices of Respondents as alleged in this complaint constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

**IN WITNESS WHEREOF**, the Federal Trade Commission has caused this complaint to be signed by the Secretary and its official seal to be affixed hereto, at Washington, DC, this twenty-fourth day of May, 2021.

By the Commission.

**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:

## Decision and 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

## Decision and Order

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****II. 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

## Decision and Order

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.

### **III. 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.

### **IV. 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

## Decision and Order

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.

**V. 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.

**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 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;

## Decision and Order

- 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.

## **VII. 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.

## Decision and Order

- 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.

**VIII. 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

## Decision and Order

on any delinquent amount arising out of this Order, in accordance with 31 U.S.C. § 7701.

**IX. 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.

**X. 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.

**XI. 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,

## Decision and Order

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.

## Decision and Order

- 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.

**XII. 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:

## Decision and 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.

**XIII. 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

## Analysis to Aid Public Comment

Respondents, pursuant to Section 604(2) of the Fair Credit Reporting Act, 15 U.S.C. § 1681b(a)(2).

**XIV. 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.

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT**

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an agreement containing a consent order with BASF SE and BASF Corporation (“BASF Respondents”). It also has accepted, subject to final approval, an agreement containing a consent order with DIEM Labs, LLC, and others (“DIEM Respondents”). The proposed consent orders have been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comment received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreements and the comments received,

## Analysis to Aid Public Comment

and will decide whether it should withdraw from one or both of the agreements and take appropriate actions or make final the agreements' proposed orders.

This matter involves Respondents' advertising for Hepaxa and Hepaxa PD capsules containing omega-3 fatty acids. The Commission's proposed complaint alleges that advertising for the Hepaxa products represented that Hepaxa reduces liver fat in most adults with Non-alcoholic Fatty Liver Disease ("NAFLD") within six months, and that Hepaxa PD reduces liver fat in most children with NAFLD within six months. The complaint further alleges that Respondents' advertising represented that tests prove that Hepaxa reduces liver fat in adults with NAFLD and that tests prove that Hepaxa PD reduces liver fat in children with NAFLD. According to the proposed complaint, these claims are false or misleading or were not substantiated at the time the representations were made, in violation of Sections 5 and 12 of the FTC Act.

The proposed orders include injunctive relief that prohibits these alleged violations and fences in similar and related conduct. The proposed orders against the BASF Respondents and DIEM Respondents are substantially similar. In both orders, "Covered Products" is defined as 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.

Part I of the orders prohibits any representation that a Covered 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, including that, at the time such representation is made, they possess and rely upon competent and reliable scientific evidence that substantiates that the representation is true.

For purposes of Part I, 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.

Part II prohibits Respondents from making any representation, other than representations covered under Part I, 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.

## Analysis to Aid Public Comment

For purposes of Part II, “competent and reliable scientific evidence” means tests, analyses, research, or studies that (1) 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.

Part III prohibits misrepresentations about tests and studies. Part IV provides Respondents a safe harbor for making claims approved by the Food and Drug Administration (“FDA”). Part V requires that, with regard to any human clinical test or study upon which Respondents rely to substantiate any claim covered by the 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 a test.

Part VI provides for monetary relief, and Part VII describes the procedures and legal rights related those payments. Together, Respondents are paying the full amount of consumer injury, \$416,914.00. DIEM Order Part VIII requires the company to provide sufficient customer information to enable the Commission to efficiently administer consumer redress to purchasers of Hepaxa and Hepaxa PD.

DIEM Order Part IX and BASF Order Part VIII require Respondents to submit acknowledgments of receipts of the order. DIEM Order Part X and BASF Order Part IX require the filing of compliance reports with the Commission, including notification to the Commission of bankruptcy filings or changes in corporate structure that might affect compliance obligations. DIEM Order Part XI and BASF Order Part X contain recordkeeping requirements. DIEM Order Part XII and BASF Order XI contain other requirements related to the Commission’s monitoring of Respondents’ order compliance. Finally, DIEM Order Part XIII and BASF Order Part XII state that the orders will remain in effect for 20 years, with certain exceptions.

The purpose of this analysis is to facilitate public comment on the orders, and it is not intended to constitute an official interpretation of the complaint or order, or to modify the order’s terms in any way.

## Complaint

## IN THE MATTER OF

**HEIDELBERGCEMENT AG,  
LEHIGH HANSON, INC.,  
LEHIGH CEMENT COMPANY LLC,  
ELEMENTIA S.A.B. DE C.V.,  
GIANT CEMENT HOLDING, INC.,  
AND  
KEYSTONE CEMENT COMPANY**

FINAL ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT AND SECTION 7 OF THE CLAYTON ACT

*Docket No. 9402; File No. 201 0006  
Complaint, May 20, 2021 – Decision, June 4, 2021*

This Order addresses the \$151 million acquisition by Lehigh Cement Company LLC, a wholly-owned subsidiary of HeidelbergCement AG, of certain assets of Keystone Cement Company, an indirectly wholly-owned subsidiary of Heidelberg. The complaint alleges that the acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act by significantly reducing competition in the market for cement, the key input in concrete, to customers in eastern Pennsylvania and western New Jersey. On June 3, 2021, Respondents terminated their Asset Purchase Agreement and withdrew the Hart-Scott-Rodino Notification and Report Forms filed for the proposed acquisition. Complaint Counsel and Respondents jointly move to dismiss the complaint as moot. The Order dismisses the complaint without prejudice.

*Participants*

For the *Commission*: Michael Barnett, Stephanie C. Bovee, Peter Colwell, Brian A. O’Dea, Christina Perez, James E. Southworth, and Ricardo A. Woolery.

For the *Respondents*: Lin Kahn, Bruce McDonald, and Thomas York, Jones Day; Stephen Pepper, Greenberg Traurig LLP; Andrew Forman, Paul, Weiss, Rifkind, Wharton & Garrison LLP.

**COMPLAINT**

Pursuant to the provisions of the Federal Trade Commission Act (“FTC Act”), and by virtue of the authority vested in it by the FTC Act, the Federal Trade Commission (“Commission”), having reason to believe that Respondents HeidelbergCement AG, Lehigh Hanson, Inc., Lehigh Cement Company LLC (collectively, “Lehigh”), Elementia S.A.B. de C.V. (“Elementia”), Giant Cement Holding, Inc. (“Giant”), and Keystone Cement Company (“Keystone”) have executed an acquisition agreement (“Acquisition Agreement”) pursuant to which Lehigh will acquire substantially all the assets of Keystone (the “Acquisition”) in violation of Section 5 of the FTC Act, 15 U.S.C. § 45, and which if consummated would violate Section 7 of the Clayton Act, 15 U.S.C. § 18, and Section 5 of the FTC Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby