

**UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION**

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.

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 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.

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. 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 (originally posted October 2018)



* * *



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[®].



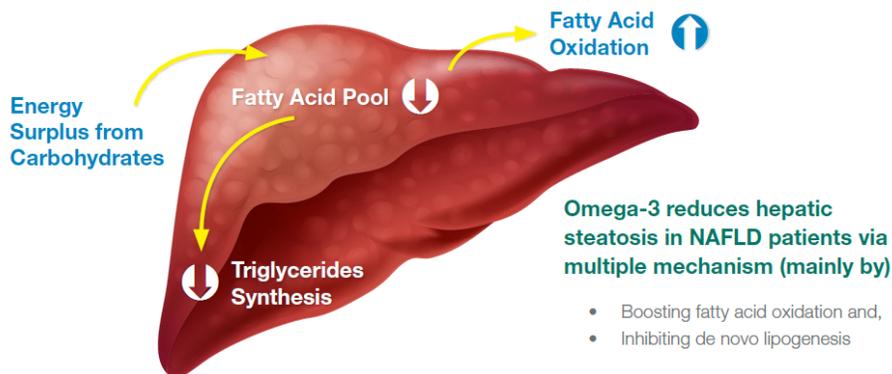
* * *

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 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.



- 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

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. ^a

In an RCT, DHA supplementation improves liver steatosis in children with NAFLD. ^b

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. ^c

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](#)

* * *

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.³



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.¹

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%

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



Tony Graetzer

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[Send email](#)

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

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.

G. LinkedIn Posts

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

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
1yr • 🔒 [+ 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
1yr • 🔒

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
1yr • 🔒 [+ 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

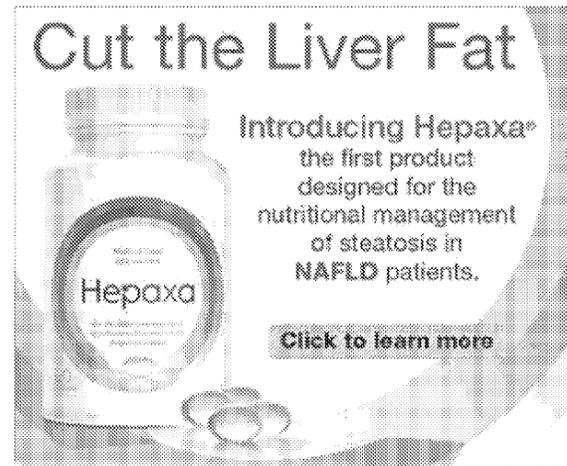
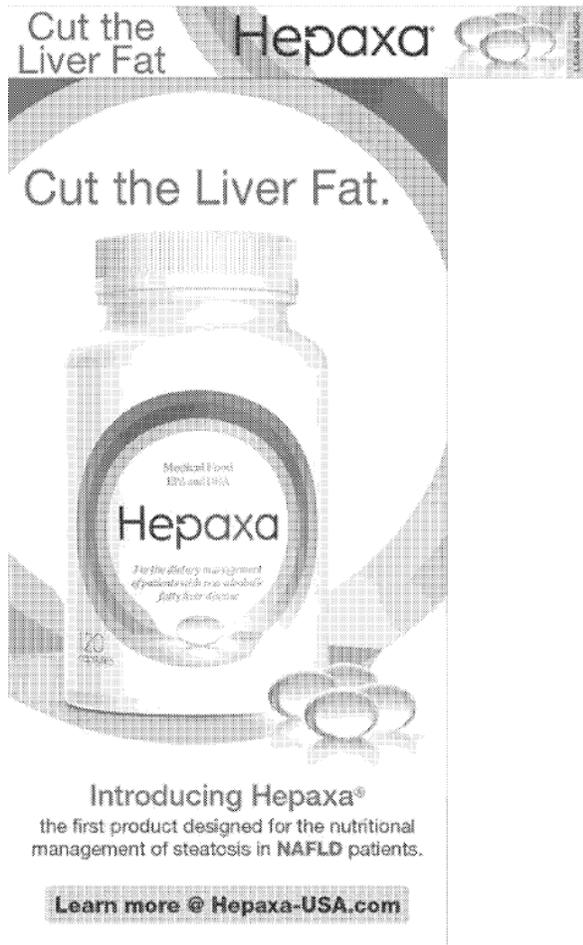
BASF Human Nutrition ✓ @BASF_nutrition · Oct 29, 2018

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/42vxvyyw



3 8

I. Online Banner Ads



9. The clinical trial referred to in Paragraphs 8.E, 8.F, and 8.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 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 8, 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 16 are false or misleading.

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 _____ day of _____, 20__.

By the Commission.

April J. Tabor
Secretary

SEAL: