

**Analysis of Proposed Consent Order to Aid Public Comment**  
***In the Matter of BASF SE et al., File No. 1923088***

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, 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.

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.