Analysis of Proposed Consent Order to Aid Public Comment
In the Matter of Bionatrol Health, LLC, FTC File No. 202 3114

The Federal Trade Commission ("FTC" or "Commission") has accepted, subject to final approval, an agreement containing a consent order with Bionatrol Health, LLC ("Bionatrol"); Isle Revive, LLC also doing business as Isle Revive CBD ("Isle Revive"); Marcelo Torre, individually and as a manager of Bionatrol and Isle Revive; and Anthony McCabe, individually (collectively, "Respondents").

The proposed consent order ("order") has been placed on the public record for 30 days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the order and the comments received, and will decide whether it should withdraw the order or make it final.

This matter involves Respondents' advertising for products containing cannabidiol ("CBD Products), including Bionatrol Full-Spectrum CBD Oil Extract. The complaint alleges that Respondents violated Sections 5(a) and 12 of the FTC Act by disseminating false and unsubstantiated advertisements claiming that their CBD Products, among other things: are safe for all users; treat pain better than prescription medicine like OxyContin; prevent and treat age-related cognitive decline, chronic pain, including arthritis pain, heart disease, hypertension, and migraines; and are "medically proven" to (a) improve anxiety, insomnia, chronic pain, hypertension, and cardiovascular health; (b) treat depression and bipolar disorder; (c) reduce age-related cognitive decline; (d) improve memory recall; and (e) reduce arthritis pain, migraines, and headaches. The complaint further alleges that Respondents misrepresented the cost to purchase one bottle of their CBD Oil Extract and unfairly charged consumers' credit cards for the additional cost without their express informed consent.

The order includes injunctive relief that prohibits these alleged violations and fences in similar and related conduct. The product coverage would apply to any dietary supplement, drug, or food that Respondents sell or market, including CBD Products.

Part I prohibits Respondents from making any representation about the efficacy of any covered product, including that such product:

A. treats, alleviates, or cures age-related cognitive decline;

B. prevents age-related cognitive decline; pain, including arthritis pain; hypertension; or migraines;

C. treats, alleviates, or cures any disease, including but not limited to bipolar disorder; pain, including arthritis pain; depression; heart disease; hypertension; and migraines;

D. replaces the need for prescription painkillers like oxycontin; or

E. is safe for all consumers,

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 requires that, with regard to any human clinical test or study ("test") 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 IV prohibits Respondents from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or other research or that any benefit of any covered product is scientifically or clinically proven.

Part V prohibits Respondents from misrepresenting, among other things, any cost to the consumer to purchase, receive, use, or return the initial good or service; that a good or service is offered on a "free," "trial," "sample," "bonus," "gift," "no obligation," "discounted" basis, or words of similar import; and any material aspect of the nature or terms of a refund, cancellation, exchange, or repurchase policy for the good or service.

Part VI prohibits Respondents from charging any consumer without obtaining the consumer's express informed consent to the charge and having created and maintained a record of such consent.

Part VII provides Respondents a safe harbor for making claims approved by the Food and Drug Administration ("FDA").

Parts VIII and IX require Respondents Bionatrol and Isle Revive to pay the Commission $20,000.00 and describes the procedures and legal rights related that payment.

Part X requires Respondents Bionatrol, Isle Revive, and Torre to send email notices to

consumers who purchased Bionatrol Full-Spectrum CBD Oil Extract informing them about the settlement.

Parts XI requires Respondents to submit an acknowledgement of receipt of the order, to serve the order on certain individuals, including all officers or directors of any business Respondents control and employees having managerial responsibilities for conduct related to the subject matter of the order, and to obtain acknowledgements from each individual or entity to which Respondents have delivered a copy of the order.

Part XII requires Respondents to file compliance reports with the Commission and to notify the Commission of bankruptcy filings or changes in corporate structure that might affect compliance obligations. **Part XIII** contains recordkeeping requirements for accounting records, personnel records, consumer correspondence, advertising and marketing materials, and claim substantiation, as well as all records necessary to demonstrate compliance or non-compliance with the order. **Part XIV** contains other requirements related to the Commission's monitoring of Respondents' order compliance. **Part XV** provides the effective dates of the order, including that, with exceptions, the order will terminate in 20 years.

The purpose of this analysis is to facilitate public comment on the order, 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.