and the marketers have made virtually no effort to possess and rely on scientific evidence to support their strong, express disease claims, as we allege in our complaint, I agree that law enforcement is appropriate.

The Commission's proposed consent orders in these matters require respondents to possess and rely on competent and reliable evidence, defined as randomized, double-blind, placebo-controlled human clinical trials to support disease and other serious health claims for these types of products in the future.[3] Although I support this requirement in these cases, for these types of claims, I caution that the Commission should impose this stringent substantiation requirement sparingly. Credible science supports the use of CBD products to treat certain conditions—specifically, the FDA has approved a drug containing CBD as an active ingredient to treat rare, severe forms of epilepsy.[4] And I understand that many research studies are currently seeking to determine whether there are other scientifically valid and safe uses of this ingredient.

I agree with my predecessors who have stated that the Commission should be careful to avoid imposing an unduly high standard of substantiation that risks denying consumers truthful, useful information, may diminish incentives to conduct research, and could chill manufacturer incentives to introduce new products to the market.[5] And I agree with the observation of my colleague Commissioner Chopra in his statement that ''[b]aseless claims give patients false hope, improperly increase or divert their medical spending, and undermine 'a competitor's ability to compete' on honest attributes.'' [6] Although I support these cases, I hope that the Commission's actions here, which challenge wholly unsubstantiated disease claims, do not discourage research into the potential legitimate benefits of CBD and a wide array of other products. In addition, going forward, I urge the Commission to focus our scarce resources on marketers that make strong, express claims about diseases and serious health issues with little to no scientific support and engage in deceptive practices that cause substantial consumer injury.

[FR Doc. 2020–28543 Filed 12–23–20; 8:45 am]

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[3] *See, e.g.,* Part I of Proposed Order, In the Matter of Bionatrol Health, LLC, et. al. (Dec. 2020).

[4] *See* FDA Press Release, *FDA approves first drug comprised of an active ingredient derived from marijuana to treat rare, severe forms of epilepsy* (June 25, 2018), available at: *https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms.*

[5] *See, e.g.,* Statement of Commissioner Maureen K. Ohlhausen, *In the Matter of Health Discovery Corporation and FTC* v. *Avrom Boris Lasarow, et al.* (Feb. 2015), *https://www.ftc.gov/public-statements/2015/02/dissenting-statement-commissioner-maureen-k-ohlhausen-matter-health;* Statement of Commissioner Joshua D. Wright, *FTC* v. *Kevin Wright; HCG Platinum, LLC; and Right Way Nutrition, LLC* (Dec. 2014), *https://www.ftc.gov/public-statements/2014/12/statement-commissioner-joshua-d-wright-federal-trade-commission-v-kevin;* Statement of Commissioner Joshua D. Wright, *In the Matter of GeneLink, Inc., and foru International Corporation* (January 2014), *https://www.ftc.gov/public-statements/2014/01/statement-commissioner-joshua-d-wright-matter-genelink-inc-foru;* Statement of Commissioner Maureen K. Ohlhausen Dissenting in Part and Concurring in Part, *In the Matter of GeneLink, Inc. and foru International Corporation* (January 2014), *https://www.ftc.gov/public-statements/2014/01/statement-commissioner-maureen-k-ohlhausen-dissenting-part-concurring-part;* Dissenting Statement of Commissioner Maureen K. Ohlhausen, *FTC* v. *Springtech 77376, et al.* (July 2013), *https://www.ftc.gov/public-statements/2013/07/dissenting-statement-commissioner-maureen-k-ohlhausen; see also* J. Howard Beales, III and Timothy J. Muris, In Defense of the *Pfizer* Factors, George Mason Law & Economics Research Paper No. 12–49 (May 2012), available at: *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2087776.*

[6] *See* Statement of Commissioner Rohit Chopra Regarding the Cannabidiol (CBD) Enforcement Actions (Dec. 17, 2020).

FEDERAL TRADE COMMISSION

[File No. 202 3114]

Bionatrol Health, LLC; Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement; request for comment.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices. The attached Analysis to Aid Public Comment describes both the allegations in the complaint and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before January 27, 2021.

ADDRESSES: Interested parties may file comments online or on paper by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Please write ''Bionatrol Health, LLC, FTC File No. 202 3114'' on your comment, and file your comment online at *https://www.regulations.gov* by following the instructions on the web-based form. If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Keith Fentonmiller (202–326–2775), Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC website at this web address: *https://www.ftc.gov/news-events/commission-actions.*

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before January 27, 2021. Write ''Bionatrol Health, LLC, FTC File No. 202 3114'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the *https://www.regulations.gov* website.

Because of the public health emergency in response to the COVID–19 pandemic and the agency's heightened security screening, postal mail addressed to the Commission will be subject to delay. We strongly encourage you to submit your comments online through the *https://www.regulations.gov* website.

If you prefer to file your comment on paper, write ''Bionatrol Health, LLC; File No. 202 3114'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex D), Washington, DC 20580; or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment to the

Commission by courier or overnight service.

Because your comment will be placed on the publicly accessible website at *https://www.regulations.gov,* you are solely responsible for making sure your comment does not include any sensitive or confidential information. In particular, your comment should not include sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure your comment does not include sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''trade secret or any commercial or financial information which . . . is privileged or confidential''—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled ''Confidential,'' and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on the *https://www.regulations.gov* website—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from that website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the FTC website at *http://www.ftc.gov* to read this Notice and the news release describing the proposed settlement. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before January 27, 2021. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *https://www.ftc.gov/site-information/privacy-policy.*

Analysis of Proposed Consent Order To Aid Public Comment

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 so that interested persons may submit comments. 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. Part 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 aid public comment on the order. It is not intended to constitute an official interpretation of the complaint or order, or to modify in any way the order's terms.

By direction of the Commission.

April J. Tabor,

Acting Secretary.

Statement of Commissioner Rohit Chopra [1]

Summary

- When companies lie about the effectiveness of their treatments for serious conditions, this harms patients and diverts sales away from firms that tell the truth.
- Congress gave the FTC a new authority to crack down on abuses in the opioid treatment industry, but the agency has not prioritized this issue. This should change.
- The FTC can increase its effectiveness when it comes to health claims by shifting resources away from small businesses and by deploying the unused Penalty Offense Authority.

Today, the Federal Trade Commission is taking action against several outfits regarding their outlandish—and unlawful—claims about cannabidiol (CBD). While CBD is currently the subject of considerable scientific research, there is no evidence yet that CBD can treat or cure cancer, Alzheimer's, or other serious diseases. Baseless claims give patients false hope, improperly increase or divert their medical spending, and undermine ''a competitor's ability to compete'' on honest attributes.[2]

I support these actions and congratulate those who made them a reality. Going forward, however, the FTC will need to refocus its efforts on health claims by targeting abuses in the substance use disorder treatment industry, shifting attention toward large businesses, and making more effective use of the FTC's Penalty Offense Authority.

First, COVID–19 and the resulting economic and social distress are fueling new concerns about substance use disorders. In particular, there are signs that the pandemic is leading to greater dependence on opioids.[3] It is critical that the FTC take steps to prevent exploitation of patients seeking treatment for substance use disorders.

I am particularly concerned about abusive practices in the for-profit opioid treatment industry, and believe this should be a high priority. This industry has grown exponentially by profiting off those suffering from addiction. Many of these outfits use lead generators to steer Americans into high-cost, subpar treatment centers, and some even hire intermediaries—so-called ''body brokers''—who collect kickbacks from this harmful practice.[4]

More than two years ago, Congress passed the SUPPORT for Patients and Communities Act. Among other provisions, the Act authorized the Commission to seek civil penalties, restitution, damages, and other relief against outfits that engage in misconduct related to substance use disorder treatment.[5] The Commission is well positioned to help shut down these abuses, ensure they are not profitable,

[1] *In the Matter of EasyButter, LLC et al.,* Comm'n File No. 2023047; *In the Matter of Reef Industries, Inc. et al.,* Comm'n File No. 2023064; *In the Mater of Steves Distributing, LLC et al.,* Comm'n File No. 2023065; *In the Matter of CBD Meds, Inc. et al.,* Comm'n File No. 2023080; *In the Matter of Epichouse, LLC et al.,* Comm'n File No. 2023094; *In the Matter of Bionatrol Health, LLC et al.,* Comm'n File No. 2023114.

[2] *In re Pfizer, Inc.,* 81 F.T.C. 23, 62 (1972).

[3] *See, e.g.,* Jon Kamp & Arian Campo-Flores, *The Opioid Crisis, Already Serious, Has Intensified During Coronavirus Pandemic,* Wall Street J. (Sept. 8, 2020), *https://www.wsj.com/articles/the-opioid-crisis-already-serious-has-intensified-during-coronavirus-pandemic-11599557401; Issue brief: Reports of increases in opioid- and other drug-related overdose and other concerns during COVID pandemic,* AMERICAN MEDICAL ASSOCIATION (last updated on Oct. 31, 2020), *https://www.ama-assn.org/delivering-care/opioids/covid-19-may-be-worsening-opioid-crisis-states-can-take-action.*

[4] For example, recent reporting describes the ''Florida Shuffle,'' where treatment facilities pay brokers to recruit patients through 12-step meetings, conferences, hotlines, and online groups, leading to serious harm. *See* German Lopez, *She wanted addiction treatment. She ended up in the relapse capital of America,* VOX (Mar. 2, 2020), *https://www.vox.com/policy-and-politics/2020/3/2/21156327/florida-shuffle-drug-rehab-addiction-treatment-bri-jayne. See also* Letter from Commissioner Chopra to Congress on Deceptive Marketing Practices in the Opioid Addiction Treatment Industry (July 28, 2018), *https://www.ftc.gov/public-statements/2018/07/letter-commissioner-chopra-congress-deceptive-marketing-practices-opioid* (calling on the FTC to do more to tackle this problem).

[5] Public Law 115–271 §§ 8021–8023 (codified in 15 U.S.C. 45d). The Act also allows the Commission to prosecute deceptive marketing of opioid treatment products. Notably, a number of respondents in this sweep are alleged to have made claims that CBD could replace OxyContin.

and hold predatory actors and their enablers to account.[6]

Unfortunately, the Commission has brought zero cases under this new authority. While I have supported actions like this one that challenge baseless CBD claims, as well as previous actions charging that pain relief devices and similar products were sold deceptively,[7] I am concerned that we have largely ignored Congressional concerns about unlawful opioid treatment practices. I urge my fellow Commissioners to change course on our enforcement priorities, especially given our limited resources.

Second, the FTC should focus more of its enforcement efforts on larger firms rather than small businesses. Today's actions focus on very small players, some of which are defunct. While I appreciate that small businesses can also harm honest competitors and families, they are often judgment-proof, making it unlikely victims will see any relief.[8] I am confident that FTC staff can successfully challenge powerful, well-financed defendants that break the law.

Finally, the Commission should reduce the prevalence of unlawful health claims by triggering civil penalties under the FTC's Penalty Offense Authority.[9] Under the Penalty Offense Authority, firms that engage in conduct they know has been previously condemned by the Commission can face civil penalties, in addition to the relief that we typically seek.[10] For example, the Commission routinely issues warning letters to businesses regarding unsubstantiated health claims. Future warning letters can be more effective if they include penalty offense notifications.

The Commission has repeatedly found that objective claims require a reasonable basis,[11] and apprising firms of these findings—along with a warning that noncompliance can result in penalties—makes it significantly more likely they will come into compliance voluntarily. In fact, when the Commission employed this strategy four decades ago, it reportedly resulted in a ''high level of voluntary compliance achieved quickly and at a low cost.'' [12] Going forward, we should pursue this strategy.

I thank everyone who made today's actions possible, and look forward to future efforts that address emerging harms using the full range of our tools and authorities.[13]

Concurring Statement of Commissioner Christine S. Wilson

Today the Commission announces six settlements with marketers of cannabidiol (CBD) products resolving allegations that they made false, misleading, and/or unsubstantiated express disease claims for their products. I support these cases because accurate and complete information about products contributes to the efficient functioning of the market and facilitates informed consumer decision-making. In contrast, deceptive or false claims inhibit informed decision-making and may cause economic injury to consumers.

The Commission's complaints in these matters allege that the marketers claimed their products could treat, prevent, or cure diseases or serious medical conditions, including cancer, heart disease, Alzheimer's, diabetes, and Parkinson's disease, and that scientific research or clinical studies supported these claims. In fact, according to the Commission's complaints, the proposed respondents did not conduct scientific research on the efficacy of their products to treat these diseases or conditions. In addition, the complaints allege that some of the proposed respondents claimed that their products could be taken in lieu of prescription medication. The Commission has been working with the FDA, and on its own, to combat false and unsubstantiated claims for CBD products, including through warning letters [1] and a law enforcement action.[2] Here, where consumers may have foregone proven measures to address serious diseases and the marketers have made virtually no effort to possess and rely on scientific evidence to support their strong, express disease claims, as we allege in our complaint, I agree that law enforcement is appropriate.

The Commission's proposed consent orders in these matters require respondents to possess and rely on competent and reliable evidence, defined as randomized, double-blind, placebo-controlled human clinical trials to support disease and other serious health claims for these types of products in the future.[3] Although I support this requirement in these cases, for these types of claims, I caution that the Commission should impose this stringent substantiation requirement sparingly. Credible science supports the

[6] Given public reports regarding private equity rollups of smaller opioid treatment facilities, the Commission can also examine whether anticompetitive M&A strategies are leading to further patient harm. *See* Statement of Commissioner Rohit Chopra Regarding Private Equity Roll-ups and the Hart-Scott-Rodino Annual Report to Congress, Comm'n File No. P110014 (July 8, 2020), *https://www.ftc.gov/public-statements/2020/07/statement-commissioner-rohit-chopra-regarding-private-equity-roll-ups-hart.*

[7] Press Release, Fed. Trade Comm'n, Marketers of Pain Relief Device Settle FTC False Advertising Complaint (Mar. 4, 2020), *https://www.ftc.gov/news-events/press-releases/2020/03/marketers-pain-relief-device-settle-ftc-false-advertising.*

[8] In one of these matters, the respondents are paying nothing.

[9] 15 U.S.C. 45(m)(1)(b).

[10] *See* Rohit Chopra & Samuel A.A. Levine, The Case for Resurrecting the FTC Act's Penalty Offense Authority (Oct. 29, 2020), *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3721256.* Particularly given challenges to the FTC's 13(b) authority, incorporating a penalty offense strategy can safeguard the Commission's ability to seek strong remedies against lawbreakers.

[11] This requirement was first established in the Commission's 1972 *Pfizer* decision, and it has been affirmed repeatedly. *Pfizer, Inc., supra* note 2 (finding that ''[f]airness to the consumer, as well as fairness to competitors'' compels the conclusion that affirmative claims require a reasonable basis); *In re Thompson Medical Co.,* 104 F.T.C. 648, 813 (1984) (collecting cases), aff'd, 791 F.2d 189 (D.C. Cir. 1986). Appended to *Thompson Medical* was the Commission's Policy Statement Regarding Advertising Substantiation, which states that ''a firm's failure to possess and rely upon a reasonable basis for objective claims constitutes an unfair and deceptive act or practice in violation of Section 5 of the Federal Trade Commission Act.'' *Id.* at 839. This standard continues to govern the Commission's approach to substantiation, as recently reaffirmed in the Commission's final order against POM Wonderful. *In re POM Wonderful LLC et al.,* 155 F.T.C. 1, 6 (2013).

[12] Commissioner Bailey made this observation in the context of opposing industry efforts to repeal this authority, an authority she described as an ''extremely effective and efficient way to enforce the law.'' Testimony of Commissioner Patricia P. Bailey Before the Subcomm. on Com., Tourism and Transp. of the Comm. on Energy and Com. of the H.R. Concerning the 1982 Reauthorization of the Fed. Trade Comm'n, at 11 (Apr. 1, 1982), *https://www.ftc.gov/system/files/documents/public_statements/693551/19820401_bailey_testimony_before_the_subcorrmittee_on_commerce_subcommittee_on_commerce_touri.pdf.*

[13] My colleague, Commissioner Christine S. Wilson, has issued a statement in this matter. I agree that the Commission should not prioritize close-call substantiation cases, especially those involving small businesses.

[1] Press Release, *FTC and FDA Warn Florida Company Marketing CBD Products about Claims Related to Treating Autism, ADHD, Parkinson's, Alzheimer's, and Other Medical Conditions,* Oct. 22, 2019, available at *https://www.ftc.gov/news-events/press-releases/2019/10/ftc-fda-warn-florida-company-marketing-cbd-productsabout-claims;* Press Release, *FTC Sends Warning Letters to Companies Advertising Their CBD-Infused Products as Treatmentsfor Serious Diseases, Including Cancer, Alzheimer's, and Multiple Sclerosis,* Sept. 10, 2019, available at *https://www.ftc.gov/news-events/press-releases/2019/09/ftc-sends-warning-letters-companies-advertising-their-cbdinfused;* Press Release, *FTC Joins FDA in Sending Warning Letters to Companies Advertising and Selling Products Containing Cannabidiol (CBD) Claiming to Treat Alzheimer's, Cancer, and Other Diseases,* Apr. 2, 2019, available at *https://www.ftc.gov/news-events/press-releases/2019/04/ftc-joins-fda-sending-warning-letters-companiesadvertising.*

[2] Press Release, *FTC Order Stops the Marketer of ''Thrive'' Supplement from Making Baseless Claims It Can Treat, Prevent, or Reduce the Risks from COVID–19,* July 10, 2020, available at *https://www.ftc.gov/newsevents/press-releases/2020/07/ftc-order-stops-marketer-thrive-supplement-making-baseless-claims.*

[3] *See, e.g.,* Part I of Proposed Order, In the Matter of Bionatrol Health, LLC, et. al. (Dec. 2020).

use of CBD products to treat certain conditions—specifically, the FDA has approved a drug containing CBD as an active ingredient to treat rare, severe forms of epilepsy.[4] And I understand that many research studies are currently seeking to determine whether there are other scientifically valid and safe uses of this ingredient.

I agree with my predecessors who have stated that the Commission should be careful to avoid imposing an unduly high standard of substantiation that risks denying consumers truthful, useful information, may diminish incentives to conduct research, and could chill manufacturer incentives to introduce new products to the market.[5] And I agree with the observation of my colleague Commissioner Chopra in his statement that ''[b]aseless claims give patients false hope, improperly increase or divert their medical spending, and undermine 'a competitor's ability to compete' on honest attributes.'' [6] Although I support these cases, I hope that the Commission's actions here, which challenge wholly unsubstantiated disease claims, do not discourage research into the potential legitimate benefits of CBD and a wide array of other products. In addition, going forward, I urge the Commission to focus our scarce resources on marketers that make strong, express claims about diseases and serious health issues with little to no scientific support and engage in deceptive practices that cause substantial consumer injury.

[FR Doc. 2020–28544 Filed 12–23–20; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Formative Data Collections for ACF Program Support (OMB #0970–0531)

AGENCY: Office of Planning, Research, and Evaluation, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF) proposes to revise the existing overarching generic clearance for Formative Data Collections for ACF Program Support (OMB #0970–0531) to increase the estimated number of respondents and, therefore, the overall burden estimate.

DATES: *Comments due within 30 days of publication.* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

SUPPLEMENTARY INFORMATION:

Description: The goals of the generic information collections under this approval are to obtain information about program and grantee processes or needs, and to inform the following types of activities, among others:

- Delivery of targeted assistance and workflows related to program and grantee processes, and the development and refinement of recordkeeping and communication systems.
- Planning for provision of programmatic or evaluation-related training or technical assistance (T/TA).
- Obtaining grantee or other stakeholder input on the development of program performance measures.
- Use of rapid-cycle testing activities to strengthen programs in preparation for summative evaluations.

ACF uses a variety of techniques such as semi-structured discussions, focus groups, surveys, templates, open-ended requests, and telephone or in-person interviews, in order to reach these goals.

Following standard OMB requirements, OPRE will submit a change request for each individual data collection activity under this generic clearance. Each request will include the individual instrument(s), a justification specific to the individual information collection, and any supplementary documents. OMB should review requests within 10 days of submission.

Respondents: Example respondents include: Current or prospective service providers, training or T/TA providers, grantees, contractors, current and potential participants in ACF programs or similar comparison groups, experts in fields pertaining to ACF programs, key stakeholder groups involved in ACF projects and programs, individuals engaged in program re-design or demonstration development for evaluation, state or local government officials, or others involved in or prospectively involved in ACF programs.

Instrument	Estimated total number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Semi-Structured Discussions and Focus Groups	5,000	1	2	10,000
Interviews	2,500	1	1	2,500
Questionnaires/Surveys	2,500	1.5	.5	1,875
Templates and Open-ended Requests	650	1	10	6,500

[4] *See* FDA Press Release, *FDA approves first drug comprised of an active ingredient derived from marijuana to treat rare, severe forms of epilepsy* (June 25, 2018), available at: *https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms.*

[5] *See, e.g.,* Statement of Commissioner Maureen K. Ohlhausen, *In the Matter of Health Discovery Corporation and FTC* v. *Avrom Boris Lasarow, et al.* (Feb. 2015), *https://www.ftc.gov/public-statements/2015/02/dissenting-statement-commissioner-maureen-k-ohlhausen-matter-health;* Statement of Commissioner Joshua D. Wright, *FTC* v. *Kevin Wright; HCG Platinum, LLC; and Right Way Nutrition, LLC* (Dec. 2014), *https://www.ftc.gov/public-statements/2014/12/statement-commissioner-joshua-d-wright-federal-trade-commission-v-kevin;* Statement of Commissioner Joshua D. Wright, *In the Matter of GeneLink, Inc., and foru International Corporation* (January 2014), *https://www.ftc.gov/public-statements/2014/01/statement-commissioner-joshua-d-wright-matter-genelink-inc-foru;* Statement of Commissioner Maureen K. Ohlhausen Dissenting in Part and Concurring in Part, *In the Matter of GeneLink, Inc. and foru International Corporation* (January 2014), *https://www.ftc.gov/public-statements/2014/01/statement-commissioner-maureen-k-ohlhausen-dissenting-part-concurring-part;* Dissenting Statement of Commissioner Maureen K. Ohlhausen, *FTC* v. *Springtech 77376, et al.* (July 2013), *https://www.ftc.gov/public-statements/2013/07/dissenting-statement-commissioner-maureen-k-ohlhausen; see also* J. Howard Beales, III and Timothy J. Muris, In Defense of the *Pfizer* Factors, George Mason Law & Economics Research Paper No. 12–49 (May 2012), available at: *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2087776.*

[6] *See* Statement of Commissioner Rohit Chopra Regarding the Cannabidiol (CBD) Enforcement Actions (Dec. 17, 2020).