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05/12/25

To: Executive Office of the President, Office of Management and Budget (OMB)
Re: Notice of Request for Information: Deregulation

Introduction

The Consumer Healthcare Products Association (CHPA) is the premier national trade association representing manufacturers and distributors of over-the-counter (OTC) medicines and dietary supplements. Our members are dedicated to upholding the highest standards of safety in the production and regulation of OTC medicines and dietary supplements. These products offer significant value to Americans and contribute to reducing costs within the American healthcare system. Access to dietary supplements and OTC medicines empowers consumers to take greater control of their health and provides substantial public health benefits.

These comments aim to address dietary supplement rules, regulations, guidance, or other federal policies that are inconsistent with statutory text or the Constitution, where costs exceed benefits, where regulations are outdated or unnecessary, or where regulations impose unforeseen burdens on American businesses.

Dietary supplements, including vitamins, minerals, amino acids, and other dietary additions, are regulated products. The marketing, manufacturing, labeling, and advertising of dietary supplements are governed by regulations enforced by the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC). It is imperative that regulations for dietary supplements are appropriately designed to balance consumer access with safety, product integrity, and informed consumer decision-making.

CHPA appreciates the opportunity to provide comments in response to the Office of Management and Budget's (OMB) Request for Information (RFI) regarding regulations that may be unnecessary, unduly burdensome, and that unnecessarily restrict access to consumer healthcare products.

List of Problematic Regulations, Guidance or Rules.

1. FDA Guidance for Industry: Distinguishing Liquid Dietary Supplements from Beverages[1]
2. FDA Guidance for Industry: Determining Whether Human Research Studies Can be Conducted without an IND[2]

[1] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-distinguishing-liquid-dietary-supplements-beverages
[2] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/investigational-new-drug-applications-inds-determining-whether-human-research-studies-can-be

3. FDA regulation 101.93 (d) regarding disclaimer placement for dietary supplements[3]
4. FDA regulation 21 CFR 101.36 regarding the requirement that Class I nutrients are present at 100 percent throughout the product's shelf-life[4]
5. FDA's Draft Guidance for Industry: NDI Enforcement Discretion[5]
6. FTC's Notice of Penalty Offense and Health Products Compliance Guidance[6]

Issue 1: FDA Guidance for Industry: Distinguishing Liquid Dietary Supplements from Beverages

FDA Center: FDA Human Foods Program

Regulated Product Category(ies): Dietary Supplements

Proposed Action: CHPA recommends that the FDA remove FDA Guidance for Industry: Distinguishing Liquid Dietary Supplements from Beverages to allow greater flexibility in the classification of liquid dietary supplements and functional beverages.

Background

Distinguishing Liquid Dietary Supplements from Beverages

FDA's guidance document titled "Guidance for Industry: Distinguishing Liquid Dietary Supplements from Beverages" stifles businesses by introducing artificial "conventional food/beverage factors" that limit the innovation potential in the functional beverages category. The guidance restricts the formulators in the functional beverage category to food ingredients, which is problematic because a significant area for innovation in the dietary supplement industry is functional beverages that include ingredients like botanicals, prebiotics, probiotics and other health promoting dietary ingredients.

a) Impact on the Industry

The artificial distinction between liquid dietary supplements and conventional beverages stifles innovation by imposing unnecessary limitations on the ingredients that can be used in functional beverages. This restriction hampers the development of new products that could provide significant health benefits to consumers. Functional beverages, which combine the convenience of liquid consumption with the health benefits of dietary supplement ingredients, represent a growing market segment with substantial potential for innovation and consumer health improvement.

b) Evidence and Examples

The functional beverage market has seen significant growth in recent years, driven by consumer demand for convenient and effective health solutions. However, the FDA's guidance limits the ability of manufacturers to explore new formulations and ingredients that could enhance the health benefits of these products. For example, the use of certain dietary supplement

[3] https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-101/subpart-F/section-101.93
[4] https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-101/subpart-C/section-101.36
[5] https://www.fda.gov/food/hfp-constituent-updates/fda-releases-draft-guidance-ndi-enforcement-discretion
[6] https://www.ftc.gov/business-guidance/resources/health-products-compliance-guidance

ingredients, like novel probiotics or herbs, in liquid form can be restricted, preventing the development of innovative products that could address specific health needs.

c) Proposed Changes

CHPA recommends that the FDA remove the guidance to allow greater flexibility in the classification of liquid dietary supplements and functional beverages. In the future, the guidance could be updated to recognize the unique benefits of functional beverages and permit the use of dietary supplement ingredients in these products. This change would encourage innovation, support the growth of the functional beverage market, and provide consumers with more options for maintaining and improving their health.

d) Conclusion

In conclusion, FDA's guidance on distinguishing liquid dietary supplements from beverages introduces unnecessary limitations that hinder innovation in the functional beverage market. By removing this FDA Guidance it will allow greater flexibility in ingredient use, which will support the growth of this important market segment and enhance consumer access to innovative health solutions. CHPA urges the OMB to consider these comments and support the proposed changes to promote innovation and consumer health in the self-care industry.

Issue 2: FDA Guidance for Industry: Determining Whether Human Research Studies Can be Conducted without an IND

FDA Center: FDA Human Foods Program, FDA Center for Biologics Evaluation and Research, and FDA Center for Drug Evaluation and Research

Regulated Product Category(ies): Dietary Supplements, Food

Proposed Action: Remove FDA Guidance for Industry: Determining Whether Human Research Studies Can be Conducted without an IND

Background

FDA's guidance document titled "Determining Whether Human Research Studies Can be Conducted without an IND" introduces unnecessary burdens on nutrition and dietary supplement researchers by forcing the industry into filing unneeded Investigational New Drug (IND) applications for nutrition research, which has significant regulatory implications.

a) Impact on the Industry

The requirement to file INDs for certain nutrition research studies imposes substantial administrative and financial burdens on researchers and the industry. This guidance complicates the process of conducting human research studies involving dietary supplements and nutrition, stifling innovation and progress in these fields. The additional regulatory requirements can deter researchers from pursuing important studies that could lead to advancements in nutrition and dietary supplement science.

b) Evidence and Examples

Several dietary supplement and nutrition groups have opposed this guidance, arguing that it introduces unnecessary burdens and regulatory hurdles. For instance, the requirement to file INDs for studies that do not involve investigational drugs but rather focus on nutritional

interventions creates confusion and misperceptions about the application of IND regulations. This has led to delays and increased costs for research projects that aim to explore the health benefits of dietary supplements and nutrition.

c) Proposed Changes

CHPA recommends that the FDA revoke this guidance to exempt nutrition research studies involving dietary supplements from the requirement to file INDs, unless the study involves investigational drugs. Any new guidance should clarify the distinction between drug research and nutrition research, ensuring that studies focused on dietary supplements and nutritional interventions are not subject to unnecessary regulatory burdens.

d) Conclusion

In conclusion, the FDA's guidance on determining whether human research studies can be conducted without an IND introduces unnecessary burdens that hinder innovation in nutrition and dietary supplement research. By revoking or revising this guidance to exempt nutrition research studies from the requirement to file INDs, the FDA can support the growth of this important research area and enhance consumer access to innovative health solutions. CHPA urges the OMB to consider these comments and support the proposed changes to promote innovation and consumer health in the self-care industry.

Issue 3: FDA regulation 101.93 (d) regarding disclaimer placement for dietary supplements

FDA Center: FDA Human Foods Program

Regulated Product Category(ies): Dietary Supplements

Proposed Action: Remove FDA regulation 101.9 (d)

Existing Regulation(s), Existing Guidance(s), or Alternative Approaches that Address Issue Proposed for Deregulation: Remove FDA regulation 101.9 (d) regarding the disclaimer placement.

Background

FDA's regulation 101.93 (d) regarding disclaimer placement for dietary supplements poses a significant challenge to the dietary supplement industry is the FDA's regulation 101.93 (d), which pertains to the placement of disclaimers on dietary supplement labels and labeling. This portion of the regulation introduces significant technical burdens and unnecessary litigation risks for manufacturers by requiring specific placement and formatting of disclaimers.

a) Impact on the Industry

The stringent requirements for disclaimer placement and formatting create significant compliance challenges for dietary supplement manufacturers. The regulation mandates that disclaimers must be placed adjacent to the statement with no intervening material or linked to the statement with a symbol (e.g., an asterisk) at the end of each such statement that refers to the same symbol placed adjacent to the disclaimer. Additionally, the disclaimer must appear on each panel or page where there is a statement, set off in a box if not adjacent to the statement, and in boldface type no smaller than one-sixteenth inch. [7] These requirements can

[7] https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-101/subpart-F/section-101.93

lead to redundancy, increased costs and complexity in label design and production, and they often result in litigation over nuanced compliance issues.

b) Proposed Changes

The requirement to place disclaimers adjacent to each statement or link them with symbols complicates label design and increases the risk of non-compliance. This has led to legal disputes and increased costs for manufacturers who must ensure that every label and piece of labeling material meets these stringent requirements. CHPA recommends that the FDA remove 101.93 (d) to simplify the requirements for disclaimer placement and formatting. Specifically, the regulation should allow for more flexibility in the placement of disclaimers, such as permitting a single disclaimer on the label or labeling material that covers all statements, without the need for symbols or adjacent placement. This change would reduce the compliance burden on manufacturers, decrease litigation risks, and allow for more efficient label design and production.

c) Conclusion

In conclusion, the FDA's regulation 101.93 (d) regarding disclaimer placement for dietary supplements introduces unnecessary burdens and litigation risks for manufacturers. By removing this part of the regulation to allow greater flexibility in disclaimer placement and formatting, the FDA can support the growth of the dietary supplement industry and enhance consumer access to innovative health solutions. CHPA urges the OMB to consider these comments and support the proposed changes to promote innovation and consumer health in the self-care industry.

Issue 4: FDA regulation 21 CFR 101.36 regarding the requirement that Class I nutrients are present at 100 percent throughout the product's shelf-life

FDA Center: FDA Human Foods Program

Regulated Product Category(ies): Dietary Supplements

Proposed Action: Remove the part of FDA regulation 21 CFR 101.36 regarding the requirement that Class I nutrients are present at 100 percent throughout the product's shelf-life

Background

The part of FDA's regulation FDA regulation 21 CFR 101.36 regarding the requirement that Class I nutrients are present at 100 percent throughout the product's shelf-life poses a significant challenge to the dietary supplement industry. This regulation requires manufacturers to ensure that added nutrients in dietary supplements, including vitamins, minerals, proteins, dietary fibers, and other dietary ingredients (i.e., Class I nutrients), are present at 100 percent of the ingredient amount declared in the Supplement Facts panel throughout the product's shelf life. This requirement has led to increased scrutiny and litigation over dietary ingredient overage amounts used to ensure products meet label claims at the end of their shelf life.

a) Impact on the Industry

Because nutrients naturally degrade over time, manufacturers often satisfy this requirement by intentionally adding additional amounts of ingredients to their supplements – known as "intentional overages." FDA permits manufacturers to include overages that "reasonably exceed" the labeled amounts, so long as these overages do not cause the product to be unsafe and

conform to GMP requirements. However, recent class action lawsuits have alleged that overages found in products were misleading in violation of consumer protection laws, leaving dietary supplement companies in a difficult position of having to defend and explain complicated GMP compliance practices.

b) Proposed Changes

The requirements for maintaining 100 percent of the labeled ingredient amounts throughout the product's shelf life create significant compliance challenges for dietary supplement manufacturers. The regulation mandates that manufacturers ensure the presence of nutrients at the declared amounts, leading to the practice of adding overages to account for nutrient degradation over time.

CHPA recommends that the FDA amend 21 CFR 101.36 to allow companies to meet label requirements at the end of shelf life with a lower, but still effective level of nutrients, such as 90 percent of labeled amounts. Specifically, the regulation should be updated to:

1. Establish a level below 100 percent for end-of-shelf-life requirements, such as 90 percent of labeled amounts.
2.

FDA previously rejected a request for a lower potency minimum of 90 percent (see May 3, 1999 Citizen Petition: Dietary Supplement Potency and FDA response, Oct. 19, 1999). However, new arguments as to why FDA should agree to this label change may exist. For example:

1. Reducing the minimum nutrient content requirement would help prevent excessive overages that may be added to ensure 100 percent of the label claim throughout shelf life, and lowering these requirements to 90 percent is still sufficient to provide the amount consumers expect.
2. FDA's requirements are at odds with US Pharmacopeia Convention (USP) requirements, which recognize that 90 percent of label claim is sufficient given the inherent variability in manufacturing and analytical testing.
3. Outside the U.S., many jurisdictions recognize the minimum value as 80-90 percent of label claim, including a number of countries in Asia – China, Japan, India – the European Union, the UK, and Russia, suggesting that allowing variability in label amounts is an acceptable way to regulate supplements.

c) Conclusion

In conclusion, the FDA's regulation 21 CFR 101.36 regarding dietary ingredient overage amounts introduces unnecessary burdens and litigation risks for manufacturers. By amending this regulation to allow greater flexibility in labeling, such as establishing a lower end-of-shelf-life requirement, the FDA can support the growth of the dietary supplement industry and enhance consumer access to innovative health solutions. CHPA urges the OMB to consider these comments and support the proposed changes to promote innovation and consumer health in the self-care industry.

Issue 5: FDA's Draft Guidance for Industry: NDI Enforcement Discretion

FDA Center: FDA Human Foods Program

Regulated Product Category(ies): Dietary Supplements

Proposed Action: Remove FDA's draft guidance NDI Enforcement Discretion

Background

FDA's draft guidance titled NDI Enforcement Discretion introduces an amnesty period for companies that FDA believes should have filed a New Dietary Ingredient (NDI) notification but did not. The amnesty period is puzzling to industry stakeholders because the NDI guidance is not finalized, and there is still debate about several key issues. The NDI Enforcement Discretion Draft Guidance should be revoked until after the FDA publishes the Final NDI Guidance, which is long overdue.

a) Impact on the Industry

The draft guidance aims to encourage manufacturers and distributors to correct past failures to submit required NDI notifications by exercising enforcement discretion for a limited time. However, this approach is problematic because the NDI guidance itself is not finalized, leading to uncertainty and confusion within the industry. The lack of clear, finalized guidance on NDI notifications creates an environment where companies are unsure of their obligations and face potential legal and regulatory risks.

The industry is awaiting FDA to address major concerns related to the agency's revised NDI draft guidance issued in August 2016. For example, the CHPA commented to FDA that a notification is not required for every individual dietary supplement that contains a new ingredient and is awaiting final guidance on the matter. And some organizations have highlighted the need for an authoritative list of pre-1994 dietary ingredients that are not subject to the NDI notification requirement. Without such a list, newer firms face difficulties in determining their NDI notification obligations.

b) Conclusion

CHPA recommends that the FDA remove the draft guidance on NDI enforcement discretion and focus on finalizing the NDI Draft Guidance from 2016. By finalizing the NDI guidance and addressing key issues, such as FDA's erroneous assertion that a separate NDI notification is required for each individual dietary supplement that contains a new ingredient, which is burdensome to industry and significantly elevates the number of NDI Notifications that FDA expects to receive by offering the enforcement discretion amnesty period. The FDA can better support the growth of the dietary supplement industry and enhance consumer access to innovative health solutions by revoking FDA's Draft Guidance for Industry: NDI Enforcement Discretion and finalizing the NDI Draft Guidance from 2016. CHPA urges the OMB to consider these comments and support the proposed changes to promote innovation and consumer health in the self-care industry.

Issue 6: FTC Notice of Penalty Offense and Health Products Compliance Guide

Federal Regulator: Federal Trade Commission

Regulated Product Category(ies): All Health Products (e.g., dietary supplements, OTC medicine, homeopathic products, etc.)

Proposed Action: Withdrawing the FTC Notice of Penalty Offenses and aligning the FTC Health Compliance Guide substantiation standards with DSHEA and long-standing regulatory guidance

Background

FTC's Health Products Compliance Guidance[8] issued in April 2023, along with FTC notices to nearly 700 marketers of over-the-counter (OTC) medicines, dietary supplements, homeopathic products, and functional foods, warning recipients of the possibility of incurring significant civil penalties if they fail to adequately substantiate their product claims in ways that run counter to litigated decisions of prior FTC administrative cases. CHPA, along with five co-petitioners, has submitted a Citizen Petition[9] urging the FTC to withdraw this Notice of Penalty Offenses.

a) Impact on the Industry

The FTC's Notice attempts to impose a substantiation standard that is prohibited by law and inconsistent with the Dietary Supplement Health and Education Act (DSHEA) and long-standing regulatory guidance from both the FDA and FTC. This approach circumvents Congress and the formal rulemaking process, creating uncertainty and confusion within the industry. The Notice fails to establish the 'actual knowledge' necessary to seek civil penalties under Section 5(m)(1)(B) of the FTC Act, and enforcing it would violate due process by failing to provide companies with fair notice of what is prohibited.

b) Evidence and Examples

CHPA and five co-petitioners, including the American Herbal Products Association (AHPA), The Food Industry Association (FMI), Natural Products Association (NPA), Personal Care Products Council (PCPC), and United Natural Products Alliance (UNPA), have opposed this FTC's Notice. They argue that the updated FTC guidance imposes a drug-level substantiation standard that is inconsistent with DSHEA and long-standing FDA and FTC guidance. Despite several court opinions holding that a more balanced, multi-factored standard remains the law, the FTC continues to push this stringent standard, threatening companies for engaging in permissible and truthful promotion of products.

c) Proposed Changes

CHPA recommends that the FTC withdraw the Notice of Penalty Offenses and reconsider its approach to substantiation standards for product claims. Specifically, the FTC should:

1. Align its substantiation standards with DSHEA and long-standing FDA and FTC guidance, recognizing that claims for nonprescription drugs and supplements do not require drug-level clinical trials.
2. Ensure that any enforcement actions are based on clear, established standards that provide companies with fair notice of what is prohibited.
3. Avoid imposing civil penalties based on vague and unclear regulatory guidance, which violates due process and creates a chilling effect on the promotion of truthful scientific information.

d) Conclusion

In conclusion, by withdrawing the FTC Notice of Penalty Offenses and aligning the FTC Health Compliance Guide substantiation standards with DSHEA and long-standing regulatory guidance, the FTC can support the growth of the dietary supplement industry and enhance consumer access to innovative health solutions. CHPA urges the OMB to consider these

[8] https://www.ftc.gov/business-guidance/resources/health-products-compliance-guidance
[9] https://www.chpa.org/news/2023/09/citizen-petition-urges-ftc-immediately-withdraw-notice-penalty-offenses-sent-hundreds

comments and support the proposed changes to promote innovation and consumer health in the self-care industry.

Summary

In conclusion, CHPA appreciates this opportunity to provide comments in response to the OMB's Request for Information on regulations that may be unnecessary, unduly burdensome, and unnecessarily reduce access to dietary supplements. In our comments CHPA emphasizes the need to revise or remove specific FDA and FTC regulations and guidance documents that hinder innovation and impose unnecessary burdens on the dietary supplement industry. By addressing these regulatory challenges, the government can enhance consumer access to innovative health solutions. CHPA urges the OMB to consider these comments and support the proposed changes to promote innovation and consumer health in the self-care industry.

Sincerely,

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