12.Jul.2022

Amber Sanford
Office of Operations
Food and Drug Administration
Three White Flint North, 10A–12M
11601 Landsdown St.
North Bethesda, MD 20852

Via: Office of Information and Regulatory Affairs (OIRA) (reginfo.gov/public/do/PRAMain), PRAStaff@ fda.hhs.gov

Regarding: 87 Federal Register 35789; FDA Docket Number FDA-2021-N-1222; Office of Management and Budget, Control Number 0910-0331.[1]

To Whom It May Concern:

The below is in response to the notice for a collection of information (the 'Notice') related to Section 403(r)(6) (21 U.S.C. 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act (FDCA) and Section 101.93 (21 CFR 101.93). These provisions require that a dietary supplement brandholder provide notice of certain information to the U.S. Food and Drug Administration (FDA) within thirty (30) days of going to market with a product that includes a nutrient deficiency claim, general well-being claims or a structure/function claim.

The FDA currently estimates that the 'average burden per response' is 45 minutes. We submit that each response takes a minimum of 1.5 hours and depending on the complexity of the evidence and product, the response may well exceed 5 hours to complete.

Please consider the submission by the brandholder to the FDA must include,

> (1) the name and address of the manufacturer, packer, or distributor of the dietary supplement product that bears the statement;
>
> (2) the text of the statement that is being made;
>
> (3) the name of the dietary ingredient or supplement that is the subject of the

[1] Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Labeling; Notification Procedures for Statement on Dietary Supplements. 13.Jun.2022, Federal Register Notice, 87 FR 35789.

statement;

(4) the name of the dietary supplement (including brand name); and,

(5) the signature of the responsible individual or the person who can certify the accuracy of the information presented, and who must certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading.

This type of submission may require coordination of multiple departments, to include, Legal, Research & Development, Quality Control, and Marketing, in addition to review and sign off by each department head. Furthermore, the individual that signs the submission to the FDA is certifying that there is substantiation for the statements included in the submission. This translates to that same responsible person reading a product's evidence file and/or other records and data to ensure that the statements are truthful and not misleading.

The agency's current estimate of 45 minutes per response is grossly underestimated. We appreciate that the agency has not had a robust response from industry to these types of Notices in times past, and hope the above is illustrative and informative to better understand the time commitment needed to satisfy the aforementioned regulatory requirements.

Thank you.

Kindest regards,

DocuSigned by:
Jeremy Johnson
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Jeremy Johnson
General Counsel
Traditional Medicinals, Inc.