OMB Control Number 0910-0331

Response to comment received to 30-day notice by:

Jeremy Johnson
General Counsel
Traditional Medicinals, Inc

FDA believes that the estimates provided in the 30-day notice (87 FR 35789; FDA Docket Number FDA-2021-N-1222) and in the supporting statement received at OIRA on June 14, 2022, are sufficient.

> RESPONSE: *We believe that there is minimal burden on respondents to gather information to meet the requirements of section 403(r)(6) of the FD&C Act. We are requesting only information that is immediately available to the manufacturer, packer, or distributor of the dietary supplement that bears a statement provided for in section 403(r)(6) on its label or in its labeling*.

To add context, the program office noted that the respondent submits the information to FDA after the dietary supplement already bears a statement on its label or in its labeling, so all of this information should be readily available. Furthermore, the responsible person should have already taken the action necessary to ensure that the statements at issue are truthful and not misleading since they are already on the bottle.