Concept Clearance - Reissue of Administrative Supplements for Research on Dietary Supplements

Supporting research to evaluate the health effects of dietary supplements and the underlying biological mechanisms by which they affect health is a congressional mandate and a key component of the Office of Dietary Supplements' (ODS) <u>Strategic Plan</u>. However, ODS does not have direct grant funding authority. This means that ODS can either co-fund grants with partner NIH ICOs or provide supplemental funding to existing NIH grants.

Based on the successful model employed by the Office of Research on Women's Health to increase the number and diversity of applications relevant to the mission of that office, ODS began issuing funding opportunity announcements (FOAs) for administrative supplements to funded NIH grants in 2015 (<u>PAR-14-201</u>, <u>PA-15-258</u>, <u>PA-16-319</u>, <u>PA-17-307</u>, and more recently, <u>PA-18-817</u>).

The purpose of these FOAs is to support research in which the primary emphasis is on dietary supplements and/or their ingredients in health maintenance and disease prevention. However, parent awards need not be focused on dietary supplements. Research is not limited to specific health conditions, organ systems or population groups. ODS supports all types of research, including pre-clinical, clinical, behavioral, and epidemiological. Additionally, ODS supports research and training programs that build future research capacity for studying the role of dietary supplements in health and disease prevention. Sixteen NIH Institutes, Centers, and Offices (ICOs) have joined <u>PA-18-817</u> (FIC, NCCIH, NCI, NEI, NHLBI, NIA, NIAAA, NIAID, NIAMS, NIBIB, NICHD, NIDCD, NIDCR, NIDDK, NIEHS, and ORIP) and have expressed interest in continuing to participate on the reissued FOA.

Key aspects of the proposed reissued FOA:

- Proposed research must be within the scope of the parent grant
- By definition, dietary supplements are intended to be ingested
- Dietary supplements must be studied in physiologically relevant forms and concentrations
- Dietary supplements must be rigorously identified and characterized to ensure reproducibility of the research. Documentary evidence of the composition and identity of materials must be provided (product integrity information)
- Budget limited to \$100,000 direct costs for up to one year
- Must have 18 months remaining on the parent grant at the time of submission
- 58 Funding mechanisms are eligible

Between October 2019 and January 2020, ODS received 55 applications from 14 ICOs in response to <u>PA-18-817</u>. ODS funded 37 meritorious applications (67% success rate) for 7 different funding mechanisms (R01, R21, K01, P30, P50, P51, and U01).

Based on the success of <u>PA-18-817</u>, ODS requests concept clearance from the Councils of Councils to reissue this FOA entitled, "Administrative Supplements for Research on Dietary Supplements."