

Request for Approval under the “Generic Clearance for the Collection of Routine Customer Feedback” (OMB#: 0925-0648 Expiration Date: 03/2018)

TITLE OF INFORMATION COLLECTION:

Analytical Methods and Reference Materials Program Stakeholder Interviews

PURPOSE:

The Analytical Methods and Reference Materials Program (AMRM) was created by the Office of Dietary Supplements (ODS) at the National Institutes of Health. The AMRM program’s purpose is to assist a target audience of industry, researchers, and regulators through the development, validation, and dissemination of analytical approaches for the quantification and identification of dietary supplement ingredients and products.

Periodically ODS convenes an external Expert Review Panel (ERP) to provide critical feedback to improve the performance of the AMRM Program. The next ERP review is scheduled for later in 2017. Prior to convening the ERP, ODS intends to collect feedback on AMRM processes from key participant stakeholders via individual interviews. The purpose of these interviews is to gather first-hand experiences from those directly involved in the implementation and use of the AMRM Program’s services, in order to inform the ERP recommendations for program improvement.

DESCRIPTION OF RESPONDENTS:

Program Stakeholders from non-governmental organizations who are involved in the implementation of the ODS AMRM Program. These Stakeholders’ organizations are involved dietary supplement research, manufacturing, testing, and regulatory compliance.

TYPE OF COLLECTION: (Check one)

- | | |
|--|---|
| <input type="checkbox"/> Customer Comment Card/Complaint Form | <input type="checkbox"/> Customer Satisfaction Survey |
| <input type="checkbox"/> Usability Testing (e.g., Website or Software) | <input type="checkbox"/> Small Discussion Group |
| <input type="checkbox"/> Focus Group | <input checked="" type="checkbox"/> Other: <u>Stakeholder Feedback Interviews</u> |

CERTIFICATION:

I certify the following to be true:

1. The collection is voluntary.
2. The collection is low-burden for respondents and low-cost for the Federal Government.
3. The collection is non-controversial and does not raise issues of concern to other federal agencies.
4. The results are not intended to be disseminated to the public.
5. Information gathered will not be used for the purpose of substantially informing influential policy decisions.
6. The collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the future.

Name: Adam Kuszak

To assist review, please provide answers to the following question:

Personally Identifiable Information:

1. Is personally identifiable information (PII) collected? Yes No
2. If Yes, is the information that will be collected included in records that are subject to the Privacy Act of 1974? Yes No
3. If Applicable, has a System or Records Notice been published? Yes No

Gifts or Payments:

Is an incentive (e.g., money or reimbursement of expenses, token of appreciation) provided to participants? Yes No

ESTIMATED BURDEN HOURS and COSTS

Category of Respondent	No. of Respondents	No. of Responses per Respondent	Time per Response (in hours)	Total Burden Hours
AMRM Program Stakeholder (For Profit)	15	1	20/60	5
Totals	15	1	20/60	5

Category of Respondent	Total Burden Hours	Wage Rate*	Total Burden Cost
AMRM Program Stakeholder (For Profit)	5	40.36	201.80
Totals	5	40.36	201.80

*Cite source per bls.gov if applicable

19-0000; [Life, Physical, and Social Science Occupations](http://www.bls.gov/oes/current/naics4_541700.htm);
http://www.bls.gov/oes/current/naics4_541700.htm;
<https://www.bls.gov/oes/current/oes190000.htm>

FEDERAL COST: The estimated annual cost to the Federal government is: \$9075.90

Staff	Grade/Step	Salary	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight					
Health Policy Analyst	GS-13 Step 1	\$92,145	0.625%		\$575.90
Contractor Cost					
Evaluation Consultant		\$170/hr.	50 hours	0	\$8500.00
Travel					0
Other Cost					0
Totals					\$9075.90

If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:

The selection of your targeted respondents

1. Do you have a customer list or something similar that defines the universe of potential respondents and do you have a sampling plan for selecting from this universe?
 Yes No

If the answer is yes, please provide a description of both below (or attach the sampling plan)? If the answer is no, please provide a description of how you plan to identify your potential group of respondents and how you will select them?

The universe of potential respondents is defined as all members of the AMRM Program's Advisory Panel, Stakeholder Panel, and Working Groups. From approximately 100 total individuals, we have selected 25 key potential participants who are most actively involved with the program (serve on multiple AMRM Working Groups) and who represent different distinct user groups of the AMRM products, including: analytical testing laboratories, manufacturer/supplier scientists, academic researchers, standard-setting bodies, and dietary supplement trade associations. There is no replacement plan for participants who are unable to be interviewed.

Administration of the Instrument

1. How will you collect the information? (Check all that apply)
 Web-based or other forms of Social Media
 Telephone
 In-person
 Mail
 Other, Explain
2. Will interviewers or facilitators be used? Yes No
Please make sure that all instruments, instructions, and scripts are submitted with the request.