

Act (21 U.S.C. 360b). Requests for meetings and teleconferences about NAD submissions are currently submitted on paper to CVM.

This guidance document describes the procedure for persons to submit a request for a meeting or teleconference electronically on FDA Form No. 3489.

The information sponsors should include on the form includes the sponsor's name and address, a list of agency participants, an agenda, and notification of audiovisual equipment that will be needed. The form has been updated to allow sponsors to indicate whether the request amends a previous

request for a meeting and to allow for consistency across forms. The likely respondents to this collection of information are new animal drug sponsors.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Form No.	No. of Respondents	Annual Frequency per Respondent	Total Annual Responses	Hours per Response	Total Hours
FDA Form 3489	12	14	168	0.69	116

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimates in table 1 of this document resulted from discussions with new animal drug sponsors. The estimated burden includes requests for meetings or teleconferences submitted by e-mail and on paper.

Dated: July 30, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Notice of Call for Applications for the Director's Council of Public Representatives

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The National Institutes of Health (NIH), the Federal Government's primary agency for supporting and conducting medical research leading to the improvement in the Nation's health, has established a national advisory council—the Director's Council of Public Representatives (COPR). The Chair of the COPR is the Director of the NIH. This notice describes the process for the selection of new members of the COPR that the NIH will use as current members complete their terms.

**DATES:** The application deadline is September 15, 2003—all applications must be postmarked on or before September 15, 2003; the notification of selection and term start date will be in early spring 2004; and the first COPR meeting date for new members is April 29-30, 2004.

**FOR FURTHER INFORMATION CONTACT:** NIH Director's Council of Public Representatives (COPR), c/o Palladian

Partners, Inc., 1010 Wayne Avenue, Suite 1200, Silver Spring, MD, 20910, telephone (301) 650-8660, fax (301) 650-8676, e-mail [COPR@palladianpartners.com](mailto:COPR@palladianpartners.com). If you are interested in serving as a member of the COPR, please contact Palladian Partners, Inc., to have an application mailed to you or go on-line to [http://copr.nih.gov/application\\_process.shtm](http://copr.nih.gov/application_process.shtm) to access the COPR application instructions. If you have questions about your application or the submission process, please feel free to contact the staff working on this project by mail, telephone, fax, or e-mail, as indicated in the above information.

**ADDRESSES:** Please mail your completed application to NIH Director's Council of Public Representatives (COPR), c/o Palladian Partners, Inc., 1010 Wayne Avenue, Suite 1200, Silver Spring, MD, 20910, telephone (301) 650-8660, fax (301) 650-8676, e-mail [COPR@palladianpartners.com](mailto:COPR@palladianpartners.com).

**SUPPLEMENTARY INFORMATION:** The NIH Director created the COPR in 1999 as an important forum for information exchange between the public and the NIH at the highest level. The COPR consists of up to 21 individuals who are selected from among the many diverse communities that benefit from, and have an interest in, public input relevant to NIH research, programs, and activities. The COPR is an important avenue for representatives of the public to advise the NIH Director on the viewpoints, input, and feedback of the broader public regarding issues of public importance and relevance to emerging health and science priorities identified by the NIH Director and/or the COPR. COPR members also serve as NIH ambassadors by taking information from the NIH back to the broader public. COPR terms are typically, but not always, three years.

The minimum eligibility criteria are that the applicant must:

- Have some interest in the work of the NIH (such as being a patient or family member of a patient; a care giver; a volunteer in the health or science arena; a scientist or student of science; or a health communicator, educator or professional in the medical field; but certainly not limited to these examples).

- Be in a position (formally or informally) to communicate regularly with the broader public or segments of the public about the activities of the COPR and the NIH.

- Commit to participating fully in activities of the COPR, including COPR meeting discussions and conference calls, outreach activities, and working group activities that will take time in addition to COPR meeting attendance twice a year.

In addition, COPR members—while participating in COPR activities—will have to agree to subordinate disease-specific or program-specific interests to broader, crosscutting matters of importance to the NIH, such as public input, public participation, and public trust in the research enterprise. Also, members of the COPR will have to agree to be responsive to special charges from the NIH Director in priority issue areas. COPR members must also agree to represent as broad a “public viewpoint” as possible and to at least keep the spirit of this goal at the forefront during all COPR discussions and activities.

Please contact Palladian Partners, Inc., to have an application mailed to you or go on-line to [http://copr.nih.gov/application\\_process.shtm](http://copr.nih.gov/application_process.shtm) to access the COPR application instructions. The NIH Director's COPR staff is located in the Office of Communications and Public Liaison, Office of the Director, National Institutes of Health. *Application packages postmarked after September 15, 2003, will be considered in the next*