investigational new animal drugs in situations where the treated animals do not enter the human food chain immediately at the completion of the investigational study. CVM believes that monitoring of the final disposition of such food animals is consistent with its responsibility to protect the public health under the Federal Food, Drug, and Cosmetic Act. In addition, CVM believes that acceptable standards of study conduct such as those set out in 21 CFR 514.117 would include sponsors accounting for the disposition of all animals treated with investigational new animal drugs.

This guidance document describes the procedures that should be followed by sponsors who wish to file a notice of disposition electronically on FDA Form #3487. The information sponsors should include on the form includes the sponsor's name and address, and information about the investigational animals. The form has been revised at the request of the sponsors to add a box that can be checked if the submission amends a notice of disposition previously submitted to CVM and to allow for consistency across forms. The likely respondents to this collection of information are new animal drug sponsors who have conducted clinical studies under 21 CFR 511.1(b).

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section/ FDA Form	No. of Respondents	Annual Frequency per Respondents	Total Annual Responses	Hours per Response	Total Hours
3487	12	27	324	0.81	262

[1] There are no capital 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 notices of disposition submitted on paper and by e-mail.

Dated: July 30, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–20061 Filed 8–6–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0327]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on How to Use E-Mail to Submit a Request for a Meeting or Teleconference to the Office of New Animal Drug Evaluation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits public comment on the reporting requirements for sponsors electronically requesting meetings or teleconferences with the Center for Veterinary Medicine's (CVM), Office of New Animal Drug Evaluation (ONADE).

DATES: Submit written or electronic comments on the collection of information by October 6, 2003.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.fda.gov/dockets/ecomments.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, rm. 1061, 5630 Fishers Lane, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. Collection of information is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance for Industry on How to Use E-Mail to Submit a Request for a Meeting or Teleconference to the Office of New Animal Drug Evaluation—21 CFR Part 511 (OMB Control Number 0910–0452)—Extension

''Any person intending to file a new animal drug application or abbreviated application is entitled to request meetings and/or teleconferences to reach agreement regarding a submission or investigational requirement (21 U.S.C. 360b(b)(3)). Every person outside the Federal Government may request a meeting with representative(s) of FDA to discuss a matter (21 CFR 10.65(c))''.

Sponsors often meet with CVM scientists in CVM's Office of New Animal Drug Evaluation to formulate a rational approach to studies to be conducted and to discuss how to meet the statutory requirements for new animal drug approval under section 512 of the Federal Food, Drug, and Cosmetic

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[1]

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

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.

[FR Doc. 03–20062 Filed 8–6–03; 8:45 am]

BILLING CODE 4160–01–S

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.* 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* 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.*

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* 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*