

and 120 mg, and CALAN (verapamil hydrochloride) tablets, 40 mg, 80 mg, 120 mg, and 160 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petitions and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that ISOPTIN (verapamil hydrochloride) tablets, 40 mg, 80 mg, and 120 mg, and CALAN (verapamil hydrochloride) tablets, 40 mg, 80 mg, 120 mg, and 160 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that ISOPTIN (verapamil hydrochloride) tablets, 40 mg, 80 mg, and 120 mg, and CALAN (verapamil hydrochloride) tablets, 40 mg, 80 mg, 120 mg, and 160 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of ISOPTIN (verapamil hydrochloride) tablets, 40 mg, 80 mg, and 120 mg, and CALAN (verapamil hydrochloride) tablets, 40 mg, 80 mg, 120 mg, and 160 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that these drug products were not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list ISOPTIN (verapamil hydrochloride) tablets, 40 mg, 80 mg, and 120 mg, and CALAN (verapamil hydrochloride) tablets, 40 mg, 80 mg, 120 mg, and 160 mg, in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to ISOPTIN (verapamil hydrochloride) tablets, 40 mg, 80 mg, and 120 mg, and CALAN (verapamil hydrochloride) tablets, 40 mg, 80 mg, 120 mg, and 160 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: May 7, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–10552 Filed 5–18–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Evaluation of Office of Acquisitions System (OASYS) and FFRDC Contract Administration System (FCAS) Vendor Portals National Cancer Institute (NCI)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI) will publish periodic summaries of propose projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Marla Jacobson, 9609 Medical Center Drive, MSC 9742, Rockville, MD 20850 or call non-toll-free number 240–276–5267 or Email your request, including your address to: marla.jacobson@nih.gov. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency’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 those who are to respond, including the use of appropriate automated, electronic,

mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Evaluation of Office of Acquisitions System (OASYS) and FFRDC Contract Administration System (FCAS) Vendor Portals National Cancer Institute (NCI), 0925–NEW, Expiration Date XX/XX/XXXX, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The National Cancer Institute (NCI) Office of Acquisitions (OA), located within the Office of the Director (OD) in the Office of Management (OM) at the National Cancer Institute (NCI), awards and administers contracts and simplified acquisitions in support of the Institute’s mission to prevent, diagnose and treat cancer. During the acquisition process, the OA ensures that customer service is paramount, and communications are open and continuous. Currently requests and correspondence are sent to and received from vendors through email with the exception of the FFRDC Contractor who submits through the FCAS Vendor Portal which is in production. To streamline processes, increase transparency and gain efficiencies, the OA developed OASYS and FCAS vendor portals to replace processes that are handled through email (future OASYS Vendor Portal Users) and were (current FCAS Vendor Portal Users) to individual OA recipients. The FCAS Vendor Portal and in the future, the OASYS Vendor Portal will serve as a one-stop shop for transmission of requests, reports, deliverables and other correspondence due on numerous research and development, in support of R&D contracts as well as those contract vehicles awarded using various Federal Acquisition Procedures including but not limited to FAR Part 8, Required Sources of Supplies and Services, FAR Part 13, Simplified Acquisition Procedures, and FAR Part 12, Acquisition of Commercial Items. These reports and deliverables cover a wide variety of topics in the areas of cancer research including prevention, detection, diagnosis, and control.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 12,120.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hours
Registration—OASYS	Corporations	400	1	8/60	53
Registration—FCAS	Corporations	400	1	8/60	53
Survey—OASYS	Individuals	120	1	6/60	12
Survey—FCAS	Individuals	120	1	6/60	12
Data Field Information—OASYS ..	Individuals	1,249	48	6/60	5,995
Data Field Information—FCAS	Individuals	1,249	48	6/60	5,995
Totals	3,538	120,944	12,120

Dated: May 13, 2021.
Diane Kreinbrink,
Project Clearance Liaison, National Cancer Institute, National Institutes of Health.
 [FR Doc. 2021-10476 Filed 5-18-21; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; SEP-7: NCI Clinical and Translational Cancer Research.
Date: June 17-18, 2021.

Time: 9:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W104, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: Robert F. Gahl, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W104, Rockville, Maryland 20850, 240-276-7286, robert.gahl@nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; SEP-1 NCI Clinical and Translational Cancer Research.

Date: June 23, 2021.
Time: 12:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W244, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: John Paul Cairns, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W244, Rockville, Maryland 20850, 240-276-5415, paul.cairns@nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI U01 Review: Integrating Biospecimen Science Approaches into Clinical Assay.

Date: June 29, 2021.
Time: 11:00 a.m. to 4:00 p.m.
Agenda: To review and evaluate grant applications.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W116, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: Klaus B. Piontek, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W116, Rockville, Maryland 20850, 240-276-5413, klaus.piontek@nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; Aging, Cancer Initiating Cells, and Cancer Progression (U01).

Date: June 29, 2021.
Time: 12:00 p.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W606, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: Timothy C. Meeker, M.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W606, Rockville, Maryland 20850, 240-276-6464, meekert@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; SEP-10: NCI Clinical and Translational Cancer Research.

Date: July 8, 2021.
Time: 10:00 a.m. to 4:00 p.m.
Agenda: To review and evaluate grant applications.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W634, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: Michael E. Lindquist, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W634, Rockville, Maryland 20850, 240-276-5735, mike.lindquist@nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; New Cohorts to Assess Environmental Exposures and Cancer Risk and Coordinating Center (UG3/UH3 and U24).

Date: July 13, 2021.
Time: 11:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W624, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: Timothy C. Meeker, M.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W624, Rockville, Maryland 20850, 240-276-6464, meekert@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; SEP-3 NCI Clinical and Translational Cancer Research.

Date: July 20, 2021.
Time: 10:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W120, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: Majed M. Hamawy, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W120, Rockville, Maryland 20850, 240-276-6457, mh101v@nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; R13 Conference Grant Review.

Date: July 27, 2021.
Time: 11:00 a.m. to 4:30 p.m.
Agenda: To review and evaluate grant applications.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room