This guidance replaces the draft guidance of the same name that published in the **Federal Register** of May 28, 2013 (78 FR 31943). We have carefully reviewed and considered the comments that were received on the draft guidance and have made changes for clarification. In particular, our revisions clarified the scope and applicability of the guidance and key terms used in the guidance.

Regarding scope and applicability, we have clarified that the guidance is limited to commercial manufacturing activities. Although the principles articulated may be useful in approaching quality agreements for other kinds of activities, such as clinical research, development, or distribution, these are outside the scope of this particular document.

Many comments concerned the terms ''owner'' and ''contract facility.'' Although some comments recommended that this guidance adopt the terms ''contract giver'' and ''contract acceptor,'' these terms do not align with our goal of showing how the parties to a contract manufacturing arrangement can work together to define, establish, and document agreements that delineate manufacturing activities and ensure compliance with CGMP.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on Contract Manufacturing Arrangements for Drugs: Quality Agreements. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) and have been approved under OMB control number 0910–0139.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm,* or *https://www.regulations.gov/.*

Dated: November 17, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–28122 Filed 11–22–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Joint Board meeting of the National Cancer Advisory Board and NCI Board of Scientific Advisors, December 5, 2016, 4:30 p.m. to December 7, 2016, 12:00 p.m., National Cancer Institute Shady Grove, Shady Grove, 9609 Medical Center Drive, 7W116, Rockville, MD 20850 which was published in the **Federal Register** on October 31, 2016, 81 FR 75423.

The meeting notice is amended to change the date, time and location of the meeting and to cancel the *Ad Hoc* Subcommittee on Global Cancer Research on December 5, 2016. There will be a National Cancer Advisory Board *Ad hoc* Subcommittee on Clinical Investigations on December 5, 2016, from 6:00 p.m. to 7:30 p.m. at the Pooks Hill Marriott Hotel, Annapolis and Chesapeake Room, 5151 Pooks Hill Road, Bethesda, MD 20814. The Joint meeting of the National Cancer Advisory Board and NCI Board of Scientific Advisors will now be held on December 6, 2016 at the National Institutes of Health, Building 31, Conference Room 10, 31 Center Drive, Bethesda, MD 20892. The open session is from 8:30 a.m. to 3:45 p.m. The closed session will begin at 4:00 p.m. and end at 5:00 p.m. The meeting is partially closed to the public.

Dated: November 17, 2016.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–28146 Filed 11–22–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases: Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; NIDDK DDK–B Member, Conflict Application Review.

Date: December 5, 2016.

Time: 11:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Carol J. Goter-Robinson, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7347, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7791, *goterrobinsonc@extra.niddk.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; PAR 14–301: NIDDK Central Repositories Sample Access (X01).

Date: January 18, 2017.

Time: 11:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Najma Begum, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7349, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–8894, *begumn@niddk.nih.gov*.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; PAR–15–067: U01 Applications.

Date: January 24, 2017.

Time: 11:00 a.m. to 12:30 p.m.