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**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Tracy Rupp, Office of Compounding Quality and Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-3100.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

We are announcing the availability of a guidance for industry entitled “Compounding Certain Beta-Lactam Products in Shortage Under Section 503A of the Federal Food, Drug, and Cosmetic Act.” This guidance is being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C)) and 21 CFR

10.115(g)(2)). This guidance document is being implemented immediately because of the public health need for amoxicillin oral antibiotic suspension products, but it remains subject to comment in accordance with the Agency’s good guidance practices.

This guidance describes the Agency’s regulatory and enforcement priorities regarding preparation of beta-lactam oral antibiotic suspension products that appear on FDA’s drug shortage list by a licensed pharmacist in a State-licensed pharmacy or Federal facility. FDA has received a number of reports related to increased demand for amoxicillin oral antibiotic suspension products in particular. Amoxicillin oral antibiotic powder for suspension products currently appear on FDA’s drug shortage list. FDA has also received requests for clarification about preparation of compounded versions of those products from FDA-approved tablets and capsules.

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 “Compounding Certain Beta-Lactam Products in Shortage Under Section 503A of the FD&C Act.” 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. Paperwork Reduction Act of 1995**

This guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521) is not required.

##### **III. Electronic Access**

Persons with access to the internet may obtain the document at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: November 18, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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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 Meeting**

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

The meeting 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 Initial Review Group Kidney, Urologic and Hematologic Diseases D Study Section.

**Date:** February 28–March 2, 2023.

**Time:** 5:00 p.m. to 5:00 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, 2 Democracy, 6707 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

**Contact Person:** Jason D. Hoffert, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7343, 6707 Democracy Boulevard, Bethesda, MD 20817, 301-496-9010, [hoffertj@nidk.nih.gov](mailto:hoffertj@nidk.nih.gov).

Information is also available on the Institute’s/Center’s home page: [www.nidk.nih.gov/](http://www.nidk.nih.gov/), where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: November 17, 2022.

**Miguelina Perez,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

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