spanning at least seven different countries, were associated with more than 300 fatalities—mostly in children under the age of 5.[2] At this time, FDA has no indication that any contaminated products connected to these recent international incidents have entered the U.S. drug supply chain.

This guidance is intended to replace the 2007 guidance and to alert the industry that in addition to glycerin, there are other components at a high risk of contamination with DEG and EG, including, but not limited to, propylene glycol, maltitol solution, hydrogenated starch hydrolysate, and sorbitol solution (hereinafter, ''high-risk components''). This guidance provides recommendations, including analytical testing, to help pharmaceutical manufacturers, repackers, other suppliers of high-risk components, and compounders, prevent the use of glycerin and other high-risk components that are contaminated with DEG or EG.

The guidance represents the current thinking of FDA on ''Testing of Glycerin, Propylene Glycol, Maltitol Solution, Hydrogenated Starch Hydrolysate, Sorbitol Solution, and Other High-Risk Drug Components for Diethylene Glycol and Ethylene Glycol.'' 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.

action-to-protect-children-from-contaminated-medicines. The WHO has issued global medical alerts addressing these incidents in The Gambia (October 5, 2022), Indonesia (November 6, 2022), Uzbekistan (January 11, 2023), and the Marshall Islands and Micronesia (Apr 25, 2023). See *Medical Product Alert N°6/2022: Substandard (contaminated) paediatric medicines,* World Health Organization, October 5, 2022, available at *https://www.who.int/news/item/05-10-2022-medical-product-alert-n-6-2022-substandard-(contaminated)-paediatric-medicines; Medical Product Alert N°7/2022: Substandard (contaminated) paediatric liquid dosage medicines,* World Health Organization, November 2, 2022, available at *https://www.who.int/news/item/02-11-2022-medical-product-alert-n-7-2022-substandard-(contaminated)-paediatric-liquid-dosage-medicines; Medical Product Alert N°1/2023: Substandard (contaminated) liquid dosage medicines,* World Health Organization, January 11, 2023, available at *https://www.who.int/news/item/11-01-2023-medical-product-alert-n-1-2023-substandard-(contaminated)-liquid-dosage-medicines;* and *Medical Product Alert N°4/2023: Substandard (contaminated) syrup medicines,* World Health Organization, Apr 25, 2023, available at *https://www.who.int/news/item/25-04-2023-medical-product-alert-n-4-2023—substandard-(contaminated)-syrup-medicines.*

[2] See *WHO urges action to protect children from contaminated medicines,* World Health Organization, January 23, 2023, available at *https://www.who.int/news/item/23-01-2023-who-urges-action-to-protect-children-from-contaminated-medicines.*

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collection of information is subject to review by OMB under the PRA. The collection of information for CGMP requirements has been approved under OMB control number 0910–0139.

III. Electronic Access

Persons with access to the internet may obtain the guidance 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: May 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–09973 Filed 5–9–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Delegation of Authority

AGENCY: Substance Abuse and Mental Health Services Administration, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Secretary of the United States Department of Health and Human Services delegated his authorities to the Assistant Secretary for Mental Health and Substance Use within the Substance Abuse and Mental Health Services Administration (SAMHSA) on May 4, 2023. This action is necessary to complete rulemaking being undertaken in conjunction with the Drug Enforcement Administration.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Secretary of the United States Department of Health and Human Services (HHS) has delegated to the Assistant Secretary for Mental Health and Substance Use within the Substance Abuse and Mental Health Services Administration (SAMHSA) the authorities vested in the Secretary of HHS under Title 21, Chapter 13, Subchapter I, Part A, Section 802(54)(G) of the United States Code (21 U.S.C. 802(54)(G)) on May 4, 2023.

21 U.S.C. 802(54)(G) authorizes the Secretary of HHS and the Attorney General to issue regulations (including in 42 CFR chapter I, if appropriate) that define the term ''practice of telemedicine'' for purposes of Title 21, Chapter 13, Subchapter I, as the practice of medicine in accordance with applicable Federal and State laws by a practitioner (other than a pharmacist) who is at a location remote from the patient and is communicating with the patient, or health care professional who is treating the patient, using a telecommunications system referred to in section 1395m(m) of title 42, which practice is being conducted under any circumstances that the Attorney General and the Secretary have jointly, by regulation, determined to be consistent with effective controls against diversion and otherwise consistent with the public health and safety.

These authorities may not be redelegated and shall be exercised under the Department's policy on regulations and the existing delegation of authority to approve and issue regulations. In addition, I hereby ratify and affirm any actions taken by the Assistant Secretary for Mental Health and Substance Use, or other SAMHSA officials, which involved the exercise of the authorities delegated prior to the effective date of the delegation on May 4, 2023.

Xavier Becerra,

Secretary of Health and Human Services.

[FR Doc. 2023–10041 Filed 5–9–23; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

National Indian Health Outreach and Education

Announcement Type: New.

Funding Announcement Number: HHS–2023–IHS–NIHOE–0001.

Assistance Listing (Catalog of Federal Domestic Assistance or CFDA) Number: 93.933.

Key Dates

Application Deadline Date: July 10, 2023.

Earliest Anticipated Start Date: July 24, 2023.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting applications for a cooperative agreement for the National Indian Health Outreach and Education (NIHOE) program. This program is authorized under the Snyder Act, 25