

develop SOPs specific to its use of hazardous drugs.

6. USP <800>

Public comment: Several commenters offered suggestions on the document's use of USP <800>. Most were concerned that USP should be cited more often.

NIOSH response: In response to commenters, USP <800> has been cited in the document where it could be determined that it could provide new information that did not originate with NIOSH (thus avoiding circular references).

Public comment: NIOSH should be differentiating between controls for antineoplastics and other hazardous drugs.

NIOSH response: NIOSH reaffirms that this document is intended to apply to all drugs on the 2023 *List* and not just antineoplastics. No change to *Managing Exposures* has been made in response to this comment.

Public comment: One commenter suggested that guidance on performing an individual drug risk assessment that meets the USP <800> standard would be helpful as alternative containment strategies and/or work practices for specific dosage forms weren't included.

NIOSH response: NIOSH disagrees with providing guidance for "specific dosage forms" as that is beyond the scope of this general guidance document. However, the text "[t]he risk assessment should include evaluating the dosage form and identifying the probability of exposure" has been added to Sec. 5.0 Risk Assessment, for clarity.

7. Other Topics

Public comment: One commenter noted that the term "pills" is referred throughout the document, for example, on pages 38 and 66. According to the commenter, "pill" is a nonspecific, outdated term and should be replaced with the word "tablet" instead.

NIOSH response: NIOSH agrees and has made this change throughout the final *Managing Exposures*.

Public comment: Several commenters noted spelling mistakes, errors in tables, and other editorial improvements.

NIOSH response: NIOSH thanks the commenters for pointing out these errors. NIOSH has accepted all appropriate editorial, spelling, and correction comments in its revision of *Managing Exposures*.

V. Summary of Changes to Documents

A. Procedures for Developing the NIOSH List of Hazardous Drugs in Healthcare Settings

As described in the responses to comments above, only limited

clarifications were made in the *Procedures* document. Notable changes include a revision to footnote 12 to clarify that only CDER-approved drugs are included on the *List* and the addition of a new footnote 29 to clarify NIOSH's intent regarding drugs with insufficient information in the package insert to determine whether the drug meets the NIOSH definition of a hazardous drug. Other changes comprised only minor editorial improvements.

B. Managing Hazardous Drug Exposures: Information for Healthcare Settings

Changes were made to the document, *Managing Exposures*, in response to comments received. There were some reorganizations, added references and information, and clarification of recommendations, as follows:

- In response to commenters, USP <800> was cited in document where it could be determined that it had new information that did not originate with NIOSH (thus avoiding circular references). ONS 2018 was cited and listed as an additional resource.
- The language in the document was clarified to specify that each facility should conduct their own risk assessment and develop SOPs specific to their use of hazardous drugs.
- Under Administrative Control recommendations, the language was clarified that automated counting machines should be prohibited unless the automated counting machine has been evaluated and found to not release powders.
- In the recommendations on PPE, several changes were made in response to comments:
 - Gloving recommendations for receiving and unpacking were changed to a single glove.
 - Recommendation to "spray" sterile alcohol on gloves was removed.
 - Recommendation for the use of sleeves was changed to "Consider using sleeve covers if there is a gap between the gown and the glove."
 - In the Table of Control Approaches:
 - Ophthalmologic administration guidance was added.
 - Recommendation for double flushing of toilets in homes was removed and replaced with new guidance that states "Close toilet lid or use a plastic-backed absorbent pad placed over the toilet without a lid during flushing."
 - "Crushing or manipulating tablets or capsules" was moved from the compounding activity formulation column to the administering activity formulation column.

- The document was edited to highlight the potential risk from exposure to human waste products (urine, feces, vomit). The topic of Medical Surveillance was moved forward in the document under Risk Management for clarity. Three new sections were added to increase the clarity and utility of the recommendations:
 - Section 6.5 Surface Contamination
 - Section 7.1 Hazardous Waste
 - Section 7.2 Spill Control
- Chapter 9 was created to reorganize information in the previous draft for clarity:
 - Chapter 9.0 Additional Considerations for Handling Hazardous Drugs
 - Section 9.1 Home Healthcare
 - Section 9.2 Veterinary Clinics (formerly Section 8.3 Steps to reduce potential exposure to hazardous drugs)

Additional references were added as suggested by commenters and peer reviewers to provide additional resources for readers.

John J. Howard,
Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Department of Health and Human Services.

[FR Doc. 2023-08900 Filed 4-26-23; 8:45 am]
BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA Number: 93.647]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Announcement of the Intent To Award Single-Source Cooperative Agreements to Approved but Unfunded Diaper Distribution Pilot Applications From FY2022

AGENCY: Office of Community Services (OCS), Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Notice of issuance of single-source awards.

SUMMARY: The ACF, OCS, Division of Community Discretionary and Demonstration Programs (DCDDP) announces the intent to award seven single-source cooperative agreements in the aggregate amount of up to \$8,181,779 to approved but unfunded applications submitted to the Diaper Distribution Demonstration and Research Pilot (DDDRP) Notice of Funding Opportunity HHS-2022-ACF-OCS-EDA-0161.

The purpose of these awards is to evaluate the ability of community action agencies, social services agencies, and other non-profit community organizations to provide diapers and diapering supplies on a consistent basis through diaper distribution programs, while also offering support services for families with low incomes. Recipients will operate and expand diaper distribution programs for families with low incomes.

DATES: The proposed period of performance is May 1, 2023, to April 30, 2025.

FOR FURTHER INFORMATION CONTACT: Thom Campbell, Office of Community Services, 330 C Street SW, Washington, DC 20201. Telephone: 202-401-5455; Email: thom.campbell@acf.hhs.gov.

SUPPLEMENTARY INFORMATION: The above-mentioned awards will be made pursuant to Congressional intent as reflected in the Explanatory Statement (p. S8891) accompanying the Consolidated Appropriations Act, 2023:

Social Services Research and Demonstration.—The agreement continues funding for the Diaper Distribution Demonstration and Research Pilot and expects that \$10,000,000 of the funds made available for awards for direct services be made to approved but unfunded applicants of funding opportunity HHS-2022-ACF-OCS-EDA-0161, as well as technical assistance and evaluation activities for such grants.

OCS announces the intent to award the following single-source awards:

| Recipient | Award amount |
|--|----------------|
| Massachusetts Association of Community Action Programs, Boston, MA | \$1,200,000.00 |
| California Community Action Partnership Association, Sacramento, CA | 1,200,000.00 |
| Ohio Community Action Training Organization, Columbus, OH | 1,200,000.00 |
| Maryland Community Action Partnership, Annapolis, MD | 1,200,000.00 |
| Utah Community Action Partnership Association Inc, Layton, UT | 1,101,779.00 |
| Community Action Association of Alabama, Birmingham, AL | 1,200,000.00 |
| Sisseton-Wahpeton Oyate of the Lake Traverse Reservation, Agency Village, SD | 1,080,000.00 |

Statutory Authority

The DDDRП is authorized under section 1110 of the Social Security Act; 42 U.S.C. 1310. This program was first funded by Div. H, Title II of the Consolidated Appropriations Act, 2022 (Pub. L. 117-103) as a non-statutory earmark for the Social Services Research and Demonstration.

Karen D. Shields,

Senior Grants Policy Specialist, Office of Grants Policy, Office of Administration.

[FR Doc. 2023-08830 Filed 4-26-23; 8:45 am]

BILLING CODE 4184-XX-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-0145]

Agency Information Collection Activities; Proposed Collection; Comment Request; Reporting Associated With Animal Drug and Animal Generic Drug User Fees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (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 comments on the information collection provisions of FDA’s animal drug and animal generic drug user fee programs.

DATES: Either electronic or written comments on the collection of information must be submitted by June 26, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 26, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such

as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2020-N-0145 for “Reporting Associated With Animal Drug and Animal Generic Drug User Fees.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.