

studies of silver nanomaterials in animals and cellular systems. Based on review of the scientific literature, NIOSH revised the draft CIB and developed a recommended exposure limit (REL) for silver nanomaterials. The revised draft CIB was released for public review with a **Federal Register** notice on September 18, 2018 [83 FR 47174]. The notice included a request for comments from peer reviewers and the public and provided information regarding a second public meeting that was held on October 30, 2018. The purpose of the public review was to obtain comments on whether the NIOSH draft document (1) adequately and clearly described the scientific literature on the potential adverse health effects of silver nanomaterials, and (2) demonstrated that the NIOSH recommendations on occupational exposure to silver nanomaterials are consistent with current scientific knowledge. Public, stakeholder, and scientific peer reviewers were given the opportunity to submit comments to the docket by November 30, 2018.

NIOSH carefully considered the comments received on the revised draft document. Reviewers provided comments on the NIOSH assessment of the potential adverse health effects of occupational exposure to silver nanomaterials, on the data and methods NIOSH used to develop a recommended exposure limit for silver nanomaterials, on the NIOSH recommended methods for assessing and controlling exposures to silver nanomaterials in the workplace, and on the identified data gaps and future research needs. In developing the final document, NIOSH performed an additional systematic literature search in April 2019 to determine if any subsequent studies in animals or humans had been published that pertained to the quantitative risk assessment and the derivation of a REL for silver nanomaterials. No additional studies were found that impacted those topics. NIOSH responded to the public, stakeholder, and peer review comments received and developed the final document consistent with the responses to comments. These comments and the NIOSH responses are available at: <https://www.regulations.gov/search/docket?filter=cdc-2016-0001>.

The final CIB provides a comprehensive scientific review of the scientific literature pertaining to occupational exposure to silver nanomaterials. The literature includes studies of exposures to silver

nanomaterials in the workplace, toxicological effects of exposure to silver nanomaterials in experimental animal and cellular systems, and effects of particle size and other properties on the toxicological effects of silver. NIOSH assessed the potential health risks of occupational exposure to silver nanomaterials by evaluating the scientific literature. Studies in animals have shown adverse lung and liver effects associated with exposure to silver nanoparticles. Based on an assessment of those data, NIOSH developed a REL for silver nanomaterials. This new REL applies to processes that produce or use silver nanomaterials in the workplace. In addition, NIOSH continues to recommend its existing REL for total silver (metal dust and soluble compounds, as Ag) [[www.cdc.gov/niosh/npg/npgd0557.html](http://www.cdc.gov/niosh/npg/npgd0557.html)]. In the CIB, NIOSH provides recommendations on the measurement and control of occupational exposures to silver and silver nanomaterials.

NIOSH further recommends the use of workplace exposure assessments, engineering controls, safe work procedures, training, and education, and established medical surveillance approaches to prevent potential adverse health effects from occupational exposure to silver nanomaterials. NIOSH proposes research needed to fill remaining data gaps on the potential adverse health effects of occupational exposure to silver nanomaterials.

**John J. Howard,**

*Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Proposed Information Collection Activity; Refugee Support Services (RSS) and RSS Set Aside Sub-Agency List (0970-0556)**

**AGENCY:** Office of Refugee Resettlement, Administration for Children and Families, HHS.

**ACTION:** Request for public comment.

**SUMMARY:** The Administration for Children and Families (ACF) Office of

Refugee Resettlement (ORR) seeks approval for a revision to an existing information collection, requesting Refugee Support Services (RSS) grantees and RSS Set Aside grantees to provide the agency name, city, state, website, and funding amount for each contracted sub-grantee. Additionally, ORR seeks approval to have the option to make this information public. This would enhance the accessibility of refugee service provider information to eligible clients in support of the service referral responsibilities of the State Refugee Coordinators. Similar information for ORR's discretionary grants is currently made public.

**DATES:** *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

**ADDRESSES:** Copies of the proposed collection of information can be obtained and comments may be forwarded by emailing [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation (OPRE), 330 C Street SW, Washington, DC 20201, Attn: ACF Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

**SUPPLEMENTARY INFORMATION:**

*Description:* This data collection requests RSS grantees and RSS Set Aside grantees to provide the agency name, city, state, website, and funding amount for each contracted sub-grantee.

The information will be used for national resource mapping pertaining to ORR RSS funding at the local level. Improved communication and the knowledge of all local providers is important to ORR's overall oversight of the program. In addition to RSS formula funding to states and state replacement agencies who then issue sub-awards to local providers, ORR also awards discretionary grants that directly fund local refugee service providers. This report will provide ORR a complete picture of the availability all ORR resources to assist newly arrived refugees at the local level increasing our ability to identify gaps or target areas of need.

*Respondents:* State governments and replacement designees.

## ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
RSS and RSS Set Aside Sub-grantee List .....	56	3	2	336	112

*Estimated Total Annual Burden Hours:* 112.

*Comments:* The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

**Authority:** Refugee Act of 1980 [Immigration and Nationality Act, Title IV, Chapter 2 Section 412 (e)] and 45 CFR 400.28.

**Mary B. Jones,**

*ACF/OPRE Certifying Officer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2021-D-0391]

#### Oral Drug Products Administered via Enteral Feeding Tube: In Vitro Testing and Labeling Recommendations; Draft Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Oral Drug Products Administered Via Enteral Feeding Tube: In Vitro Testing and Labeling Recommendations." This draft guidance provides recommendations for consistent in vitro testing of oral drug products to demonstrate their suitability to be administered via enteral tube. In addition, it supports the development of clear product-specific enteral tube

administration instructions in labeling for administration to patients unable to ingest oral drug products.

**DATES:** Submit either electronic or written comments on the draft guidance by August 2, 2021 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

#### 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-2021-D-0391 for "Oral Drug Products Administered Via Enteral Feeding Tube: In Vitro Testing and Labeling Recommendations." Received comments 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.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**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