• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.

• *Mail:* National Institute for Occupational Safety and Health, NIOSH Docket Office, 1090 Tusculum Avenue, MS C–34, Cincinnati, Ohio 45226–1998.

Instructions: All information received in response to this notice must include the agency name and docket number (CDC–2023–0057; NIOSH–156–F). All relevant comments, including any personal information provided, will be posted without change to *https://www.regulations.gov.* Do not submit comments by email. CDC does not accept comments by email. For access to the docket to read background documents or comments received, go to *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: R. Todd Niemeier, Ph.D., National Institute for Occupational Safety and Health, MS–C15, 1090 Tusculum Avenue, Cincinnati, OH 45226. Telephone: (513) 533–8166.

SUPPLEMENTARY INFORMATION: NIOSH is requesting public comment and technical review on a draft IDLH Value Profile document for the chemical hydrogen chloride. To facilitate the review of this document, NIOSH requests comment on the following specific questions for the draft Profile document:

1. Does this document clearly outline the health hazards associated with acute (or short-term) exposures to the chemical? If not, what specific information is missing from the document?

2. Are the rationale and logic behind the derivation of an IDLH value for a specific chemical clearly explained? If not, what specific information is needed to clarify the basis of the IDLH value?

3. Are the conclusions supported by the data?

4. Are the tables clear and appropriate?

5. Is the document organized appropriately? If not, what improvements are needed?

6. Are you aware of any scientific data reported in government publications, databases, peer-reviewed journals, or other sources that should be included within this document?

The draft IDLH Value Profile was developed to provide the scientific rationale behind derivation of IDLH values for the following chemical:

Document #	Chemical	CAS #
X–XX	Hydrogen Chloride	(#7647–01–0)

The IDLH Value Profile provides a detailed summary of the health hazards of acute exposures to high airborne concentrations of the chemical and the rationale for the IDLH value.

Background: In 2013, NIOSH published Current Intelligence Bulletin (CIB) 66: Derivation of Immediately Dangerous to Life or Health (IDLH) Values [*http://www.cdc.gov/niosh/docs/2014-100/pdfs/2014-100.pdf*] [NIOSH 2013]. The information presented in this CIB represents the scientific rationale and the current methodology used to derive IDLH values. Since the establishment of the IDLH values in the 1970s, NIOSH has continued to review available scientific data to improve the protocol used to derive acute exposure guidelines, in addition to the chemical specific IDLH values.

IDLH values are based on health effects considerations determined through a critical assessment of the toxicology and human health effects data. This approach ensures that the IDLH values reflect an airborne concentration of a substance that represents a high-risk situation that may endanger workers' lives or health.

The primary steps applied in the establishment of an IDLH value include the following:

1. Critical review of human and animal toxicity data to identify potentially relevant studies and characterize the various lines of evidence that can support the derivation of the IDLH value;

2. Determination of a chemical's mode of action or description of how a chemical exerts its toxic effects;

3. Application of duration adjustments (time scaling) to determine 30-minute-equivalent exposure concentrations and the conduct of other dosimetry adjustments, as needed;

4. Experimental or other data to establish a point of departure (POD) such as lethal concentrations (*e.g.,* LC50), lowest observed adverse effect level (LOAEL), or no observed adverse effect level (NOAEL);

5. Selection and application of an uncertainty factor (UF) for POD or critical adverse effect concentration, identified from the available studies to account for issues associated with interspecies and intraspecies differences, severity of the observed effects, data quality, or data insufficiencies; and

6. Development of the final recommendation for the IDLH value from the various alternative lines of evidence, with use of a weight-of-evidence approach to all the data.

Reference

NIOSH [2013]. Current intelligence bulletin 66: derivation of immediately dangerous to life or health (IDLH) values. Cincinnati, OH: US Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication 2014–100.

Dated: August 4, 2023.

John J. Howard,

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

[FR Doc. 2023–17129 Filed 8–9–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3103]

Development of Small Dispensers Assessment Under the Drug Supply Chain Security Act; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is seeking stakeholder comments on the development of a technology and software assessment that examines the feasibility of dispensers with 25 or fewer full-time employees conducting interoperable, electronic tracing of products at the package level. FDA would like to obtain information regarding issues to be addressed in the assessment related to the accessibility of the necessary software and hardware to such dispensers; whether the necessary software and hardware is prohibitively expensive to obtain, install, and maintain for such dispensers; and if the necessary hardware and software can be integrated into business practices.

DATES: Either electronic or written comments on the notice must be submitted by September 11, 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 September 11, 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–2023–N–3103 for ''Development of Small Dispensers Assessment under the Drug Supply Chain Security Act; Request for Comments.'' 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.

• 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 Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Daniel Bellingham, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3130, *daniel.bellingham@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On November 27, 2013, the Drug Supply Chain Security Act (DSCSA) (Title II of Pub. L. 113–54) was signed into law. The DSCSA outlines steps to achieve interoperable, electronic tracing of products at the package level to identify and trace certain prescription drugs as they are distributed in the United States. Section 202 of the DSCSA added the new sections 581 and 582 to the Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee and 360eee–1). Under section 582(g)(3), FDA is required to enter into a contract with a private, independent consulting firm with expertise to conduct a technology and software assessment that looks at the feasibility of dispensers with 25 or fewer full-time employees conducting interoperable, electronic tracing of products at the package level. Under section 582(g)(1), dispensers and other trading partners will be required to, amongst other requirements, exchange transaction information and transaction statements in a secure, interoperable, electronic manner for each package; implement systems and processes for package-level verification, including the standardized numerical identifier; and implement systems and processes to facilitate the gathering of information necessary to produce the transaction information and statement for each transaction going back to the manufacturer if FDA or a trading partner requests an investigation in the event of a recall or for purposes of investigating a suspect or illegitimate product. These enhanced drug distribution security requirements are also referred to as ''enhanced product tracing'' or ''enhanced verification.''

II. Purpose of the Request for Comments

FDA is issuing this request for public comments prior to beginning the assessment, in accordance with section 582(g)(3)(D). The statement of work requires the selected firm to conduct an assessment that will address the proposed questions articulated below. In addition to commenting on the proposed questions below, stakeholders may provide comments on any aspect of the small dispenser assessment under the DSCSA.

Stakeholders that may be interested in responding to this request for information include manufacturers, repackagers, wholesale distributors, dispensers, State and Federal authorities, solution providers, and standards organizations, among others. FDA is particularly interested in receiving comments from the various sectors of the dispenser community, particularly pharmacies. FDA is seeking comments on the following proposed questions for small dispensers (*i.e.,* dispensers with 25 or fewer full-time employees). We are interested in receiving feedback on the questions themselves and whether or not they should be edited to be more useful for the assessment. FDA is also interested in any new questions that stakeholders may recommend.

• Have you begun preparations for DSCSA requirements regarding the interoperable, electronic tracing of products at the package level required under section 582(g)(1) of the FD&C Act (*i.e.,* enhanced product tracing or enhanced verification)?

• How are you currently exchanging data with your trading partners (*e.g.,* by

paper-based methods, electronic methods, or both)?

- If not currently exchanging data with trading partners in a fully electronic manner, will you be able to in the near future? If not, what are the barriers? Elaborate on why or how, as appropriate. Please specify issues related to:
- accessibility of necessary software and hardware;
- cost to obtain, install, and maintain necessary software and hardware, particularly if it is prohibitively expensive;
- integration of necessary software and hardware into business practices, such as with wholesale distributors;
- other relevant information related to feasibility of dispensers with 25 or fewer full-time employees to conduct interoperable, electronic tracing of product at the package level.
- What type of software systems and hardware do you currently utilize to facilitate the electronic exchange of DSCSA-related data for transactions of products?
- What new or modified software systems and hardware do you anticipate putting in place to comply with the interoperable, electronic tracing requirements?
- How likely are you to change and upgrade your existing software systems that are already in use so that you can comply with the interoperable, electronic tracing requirements?
- Have you or do you plan to connect your system(s) with your trading partner(s) (*e.g.,* manufacturer(s), repackager(s), or wholesale distributor(s)) in order to facilitate electronic DSCSA-related data exchange? If so, have you experienced technical issues when attempting to establish connectivity? If not, how do you or how do you plan to manage electronic DSCSA-related data received from an upstream trading partner (*e.g.,* maintain the data in your dispenser system or use a third-party agreement for another entity to confidentially maintain the DSCSA-related data on your behalf (*e.g.,* use of a secure web portal provided by your wholesale distributor))?
- Have you considered data integrity and security concerns when establishing agreements with third-party entities (*e.g.,* solution providers or wholesale distributors) for electronic data exchange and maintenance?
- Have you ever received transaction information from a trading partner, such as your wholesale distributor, that does not match the product that you received? If so, how long did it take to resolve the discrepancy on average? What if any unique challenges arose from these situations? How often does this happen?
- If you currently routinely scan a 2D data matrix barcode, how often do you receive a 2D data matrix barcode of the product identifier that cannot be scanned or read? Why are you unable to scan or read the 2D data matrix barcode (*e.g.,* barcode quality, scanner performance, software issue) and what is your process for handling these situations, including when manual steps are taken by your staff when an automated process was inadequate or failed?
- If you currently routinely scan the 2D data matrix barcode, how often you encounter a 2D data matrix barcode with missing or inaccurate data? What are the reasons for this and what is your process for handling these situations, including when manual steps are taken by your staff when an automated process was inadequate or failed?
- What new demands do you expect the DSCSA requirements in section 582(g)(1) of the FD&C Act to have on your current staff resources?
- How long do you expect it will take to train staff on the new requirements, how to use any new software or hardware, and any process changes? What additional resources do you anticipate needing to comply with the interoperable, electronic tracing requirements?
- Are there additional challenges not already identified when operationalizing new systems and processes for interoperable, electronic tracing of products at the package level required under section 582(g)(1) of the FD&C Act (*i.e.,* enhanced product tracing or enhanced verification)?

Stakeholders may provide other relevant information that may inform the development of the small dispenser assessment under the DSCSA.

Dated: August 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–17140 Filed 8–9–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–1529]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Voluntary Qualified Importer Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by September 11, 2023.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0840. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Voluntary Qualified Importer Program

OMB Control Number 0910–0840—Extension

This information collection supports implementation of FDA's Voluntary Qualified Importer Program (VQIP), a voluntary fee-based program that provides expedited review and import entry of human and animal foods into the United States. Program participants may import products to the United States with greater speed and predictability, avoiding unexpected