''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Generic Clearance for the Collection of Minimal Data Necessary for Case Data During an Emergency Response—New—Office of Public Health Data, Surveillance, and Technology (OPHDST), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

During a public health emergency response, state, tribal, local, and territorial (STLT) health departments and CDC need to exchange data on confirmed, probable, and suspected cases rapidly. Timely notifications of cases from STLT to CDC are critical to provide situational awareness at the federal level to support decision making, particularly for public health threats that escalate quickly and cross jurisdictions. To this end, collecting the minimum data necessary will provide standardization and consistency among technical approaches and Agency-wide processes. The harmonization across CDC programs and STLTs will reduce the burden on STLTs and healthcare providers from ad hoc requests for case data from CDC programs.

Section 319D of the Public Health Service Act (as amended Through Pub. L. 118–35, enacted January 19, 2024) states that CDC shall define the minimum data necessary as the Agency collaborates with STLTs and other partners to improve the appropriate near real-time electronic transmission of interoperable public health data for situational awareness and response to public health emergencies. In addition, the CDC Advisory Committee to the Director (ACD) recommends that CDC should establish the minimum data necessary for core data sources including case data to be transmitted to CDC from STLTs.

CDC requests a three-year approval for a new Generic Information Collection Request (ICR), Clearance for the Collection of Minimal Data Necessary for Case Data During an Emergency Response. This new ICR includes a request for approval for CDC to collect the minimum data necessary for confirmed, probable, and suspected cases of any disease or condition that is the subject of an emergency response. Data may be sent to CDC by STLT Health Departments through Data Collation and Integration for Public Health Event Response (DCIPHER) or other automated or non-automated mechanisms including but not limited to fax, email, secure file upload, and data entry to a secure website.

Data will be used for ongoing situational awareness and to monitor the occurrence and spread of the disease or condition. Other uses may include identifying populations or geographic areas at high risk; planning prevention and control programs and policies; and allocating resources appropriately. The data may also be used by CDC to obtain travel histories and other information to describe and manage outbreaks and conduct public health follow-up to minimize the spread of disease. The burden estimates include the time that states, territories, freely associated states, and cities will incur to submit confirmed, probable, and suspected case data for diseases or conditions that are the subject of an emergency response.

CDC requests OMB approval for an estimated 10,951 annualized burden hours for the 60 respondents. There is no cost to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
States	Submission of case data	50	365	30/60
Territories	Submission of case data	5	365	30/60
Freely Associated States	Submission of case data	3	365	30/60
Cities	Submission of case data	2	365	30/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2024–20717 Filed 9–11–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2024–OS–0035]

Submission for OMB Review; Comment Request

AGENCY: Office of the Under Secretary of Defense for Intelligence and Security (OUSD(I&S)), Department of Defense (DoD).

ACTION: 30-Day information collection notice.

SUMMARY: The DoD has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by October 15, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Reginald Lucas, (571) 372–7574, *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Certificate Pertaining to Foreign Interests; SF–328; OMB Control Number 0704–0579.

Type of Request: Revision.

Number of Respondents: 62,950.

Responses per Respondent: 1.

Annual Responses: 62,950.

Average Burden per Response: 100 minutes.

Annual Burden Hours: 104,917.

Needs and Uses: Information collection via the Standard Form (SF) 328, ''Certificate Pertaining to Foreign Interests,'' is necessary to support the execution of 32 CFR part 117, ''National Industrial Security Program (NISPOM),''

dated December 21, 2020, or equivalent. Executive Order (E.O.) 12829, as amended, ''National Industrial Security Program (NISP),'' section 202 (a) stipulates that the Secretary of Defense serves as the Executive Agent for inspecting and monitoring the contractors, licensees, and grantees who require or will require access to, or who store or will store classified information; and for determining eligibility for access to classified information of contractors, licensees, and grantees and their respective employees. Section 202 (e) also authorizes the Executive Agent to issue, after consultation with affected agencies, standard forms that will promote the implementation of the NISP.

E.O. 12829 was amended by E.O. 13691, adding the Secretary of Homeland Security as the fifth Cognizant Security Agency. Section 202 (d) of E.O. 12829 stipulates that the Secretary of Homeland Security may determine the eligibility for access to Classified National Security Information of contractors, licensees and grantees and their respective employees under a designated critical infrastructure protection program, including parties to agreements with such programs. The Secretary of Homeland Security also may inspect and monitor the contractors, grantees or licensees and facilities or may enter into written agreements with the Secretary of Defense, as Executive Agent or with the office of the Director of Intelligence/ Director of Central Intelligence Agency to inspect and monitor these programs in whole or in part on behalf of the Secretary of Homeland Security. The specific requirements necessary to protect classified information released to private industry are found in NISPOM; found in DoDI 5220.31 ''National Industrial Security Program (NISP),'' which incorporates and cancels DoD Instruction 5220.22, ''National Industrial Security Program,'' March 18, 2011, as amended. The SF 328 incorporates its usage for the NISP portion of the Classified Critical Infrastructure Protection Program as stipulated under E.O. 12829, as amended by E.O. 13691. Revisions to the SF 328 will also incorporate its usage under the DoD's Innovation initiative through the DoD Enhanced Security Program (DESP), pursuant to section 951 of Public Law 114–328 (10 U.S.C. 1564 note). The DESP is a DoD only initiative and is not part of the NISP. Companies participating under the DESP do not require a DoD contract but are required to enter into a Memorandum of Agreement. Completion of the SF 328 and submission of supporting documentation (*e.g.,* company or entity charter documents, board meeting minutes, stock or securities information, descriptions of organizational structures, contracts, sales, leases and/or loan agreements and revenue documents, annual reports and income statements, etc.) is part of the eligibility determination for access to classified information and/or issuance of an Entity Eligibility Determination (also known as a Facility Security Clearance).

Section 847 of the National Defense Authorization Act for Fiscal Year 2020 (Pub. L. 116–92), ''Mitigating Risks Related to Foreign Ownership, Control, or Influence of Department of Defense Contractors or Subcontractors,'' requires the Secretary for Defense to improve the process and procedures for the assessment and mitigation of risks related to FOCI of contractors and subcontractors doing business with the DoD, in conjunction with the Departments efforts to develop and implement an improved analytical framework for mitigating risk relating to ownership structure, as required by 10 U.S.C. 2509 and section 847 of Public Law 116–92. To fulfill the requirements of sec. 847, contractors and subcontractors must disclose to DCSA their beneficial ownership and whether they are under FOCI, and to update those disclosures when changes occur to information previously provided consistent with the requirements of the NISPOM. In addition, sec. 847 provides for the creation of other measures as necessary to be consistent with other relevant authorities, including the NISP.

The Small Business Innovation Research and Small Business Technology Transfer (SBIR/STTR) Extension Act of 2022, Public Law 117–183, section 4, ''Foreign Risk Management'' (DoD SBIR/STTR programs), requires the head of each Federal agency required to establish a SBIR or STTR program to implement a due diligence program to assess security risks presented by small business concerns seeking federal awards. These security risks includes, among other things, foreign interested-related risks. The DoD intends to utilize the SF 328 as the basis for information collection for DoD SBIR/STTR program participants to disclose their foreign interests, and to report any future changes, as appropriate. For DoD SBIR/ STTR, the DoD will use this form to collect information to conduct a risk-based due diligence review and assess security risks presented by small business concerns seeking a federally funded award through the DoD SBIR/ STTR programs. The submission will be required to be submitted as part of the SBIR/STTR solicitation package, and details concerning its submission will be included in the solicitation published to perspective submitters.

The use of the SF 328 will also be required by the forthcoming Cybersecurity Maturity Model Certification (CMMC) program, which is currently in the Rulemaking process under 32 CFR part 170. The CMMC program will require CMMC Level 2 Certification Assessments be conducted by a CMMC Third Party Assessment Organization (C3PAO), accredited by the DoD approved CMMC Accreditation Body (AB). To be accredited, the CMMC AB and all C3PAOs must receive a favorable adjudication and not be subject to a level of risk from Foreign Ownership, Control, or Influence (FOCI) as determined by the CMMC Program Management Office (PMO). DCSA will conduct the FOCI assessments for the CMMC AB and C3PAOs after they are nominated by the CMMC PMO.

The multiple authorized uses of this form will create uniformity among numerous authorities responsible for the vetting or review of companies or entities for foreign interest-related risks. In addition, it will establish more consistency among industry concerning their basic information submission requirements regarding foreign interest information.

The submission of the SF–328, and supporting documentation, may be done electronically through a government approved system of record.

Affected Public: Business or other for profit; Not-for-profit institutions.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

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

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DoD Clearance Officer: Mr. Reginald Lucas.

Requests for copies of the information collection proposal should be sent to Mr. Lucas at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: September 4, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2024–20650 Filed 9–11–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3945]

The Food and Drug Administration's Draft Strategy Document on Innovative Manufacturing Technologies

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the publication of a draft Strategy Document for public comment outlining specific actions FDA will take during fiscal years 2023–2027 to facilitate the use of innovative manufacturing technologies. As part of the Prescription Drug User Fee Act (PDUFA) Reauthorization Performance Goals and Procedures Fiscal Years 2023–2027 (PDUFA VII), FDA committed to advance the use and implementation of innovative manufacturing. In connection with this effort, on June 8, 2023, FDA participated in a public workshop on the use of innovative manufacturing technologies for products regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER), including barriers to their adoption. FDA also committed to issuing this draft Strategy Document for public comment. The actions described in the draft Strategy Document are based on lessons learned from FDA's experiences with submissions involving advanced manufacturing technologies as well as feedback from the workshop and other public input.

DATES: Either electronic or written comments on the draft Strategy Document must be submitted by November 12, 2024.

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 November 12, 2024.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–2024–N–3945 for ''FDA's Strategy Document on Innovative Manufacturing Technologies.'' 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: Elisa A. Nickum, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4521, Silver Spring, MD 20993, 301–796–4226, *Elisa.Nickum@fda.hhs.gov;* or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

Innovative manufacturing technologies—including but not limited to continuous manufacturing, distributed manufacturing, modern aseptic manufacturing equipment, and