Request for Approval under the "Generic Clearance for the Collection of Routine Customer Feedback" (OMB Control Number: 0920-1027 Exp. 08/31/2023)

Instruction: This form should be completed by the primary contact person from the Program sponsoring the collection.

DETERMINE IF YOUR COLLECTION IS APPROPRIATE FOR THIS GENERIC CLEARANCE MECHANISM:

Instruction: Before completing and submitting this form, determine first if the proposed collection is consistent with the scope of the Collection of Routine Customer Feedback generic clearance mechanism. To determine the appropriateness of using the Collection of Routine Customer Feedback generic clearance mechanism, complete the checklist below.

*If you select "yes" to all criteria in Column A, the Collection of Routine Customer Feedback generic clearance mechanism **can** be used. If you select "yes" to any criterion in Column B, the Collection of Routine Customer Feedback generic clearance mechanism **cannot** be used.*

Column A	**Column B**
The information gathered will only be used internally to CDC. [x] Yes [ ] No	Information gathered will be publicly released or published. [ ] Yes [x] No
Data is qualitative in nature and not generalizable to people from whom data was not collected. [x] Yes [ ] No	Employs quantitative study design (e.g. those that rely on probability design or experimental methods) [ ] Yes [x] No
There are no sensitive questions within this collection (e.g. sexual orientation, gender identity). [x] Yes [ ] No	Sensitive questions will be asked (e.g. sexual orientation, gender identity). [ ] Yes [x] No
Collection does not raise issues of concern to any other Federal agencies. [x] Yes [ ] No	Other Federal agencies may have equities or concerns regarding this collection. [ ] Yes [x] No
Data collection is focused on determining ways to improve delivery of services to customers of a current CDC program. [x] Yes [ ] No	Data will be used to inform programmatic or budgetary decisions, for the purpose of program evaluation, for surveillance, for program needs assessment, or for research. [ ] Yes [x] No
The collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the future. [x] Yes [ ] No	

Did you select "Yes" to all criteria in Column A?

> If yes, the *Collection of Routine Customer Feedback* generic clearance mechanism may be appropriate for your investigation. You may proceed with this form.

Did you select "Yes" to any criterion in Column B?

> If yes, the *Collection of Routine Customer Feedback* generic clearance mechanism is **NOT** appropriate for your investigation. Stop completing this form now.

TITLE OF INFORMATION COLLECTION: Division of Tuberculosis Elimination/Field Services Branch, Potential Rifampin Shortage Assessment

PURPOSE: On June 15, 2020, the U.S. Food and Drug Administration (FDA) posted information regarding the permanent discontinuation of three Sanofi-Aventis rifampin products: Rifadin® (rifampin 150 mg and 300 mg capsules); Rifamate® (a fixed-drug combination of isoniazid and rifampin), and Rifater® (a fixed-drug combination of isoniazid, rifampin, and pyrazinamide). Rifampin is a core drug in the standard regimens for drug-susceptible and isoniazid-resistant active tuberculosis (TB) and latent tuberculosis infection. Currently, FDA is determining the status of rifampin from other manufacturers.

Conducting this Assessment will inform the Division on what activities are needed in order to ensure tuberculosis patients can complete their treatment.

DESCRIPTION OF RESPONDENTS: Sixty-one (61) recipients who receive funding under the Notice of Funding Opportunity CDC-RFA-PS20-2001, **Tuberculosis Elimination and Laboratory Cooperative Agreement,** National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Division of TB Elimination. These are state and big-city tuberculosis programs who use federal funds to support personnel, equipment, travel and contractual costs, with substantial involvement and consultation by CDC staff at the Division.

TYPE OF COLLECTION: (Check one)
Instruction: Please sparingly use the Other category

[ ] Customer Comment Card/Complaint Form
[ ] Usability Testing (e.g., Website or Software
[ ] Focus Group
[ ] Customer Satisfaction Survey
[ ] Small Discussion Group
[x] Other: written assessment

CERTIFICATION:

I certify the following to be true:
1. The collection is voluntary.
2. The collection is low-burden for respondents and low-cost for the Federal Government.

3. The collection is non-controversial and does not raise issues of concern to other federal agencies.
4. The results are not intended to be disseminated to the public.
5. Information gathered will not be used for the purpose of substantially informing influential policy decisions.

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To assist review, please provide answers to the following question:

Personally Identifiable Information:
1. Is personally identifiable information (PII) collected? [ ] Yes [x] No
2. If Yes, is the information that will be collected included in records that are subject to the Privacy Act of 1974? [ ] Yes [ ] No
3. If Applicable, has a System or Records Notice been published? [ ] Yes [x] No

Gifts or Payments:
Is an incentive (e.g., money or reimbursement of expenses, token of appreciation) provided to participants? [ ] Yes [x] No

If Yes: Please describe the incentive. If amounts are outside of customary incentives, please also provide a justification

BURDEN HOURS

Category of Respondent	**No. of Respondents**	**Participation Time**	**Burden**
Tuberculosis program manager/controller or designee	61	1 hour	61
		Semi-annually	X 2
Totals	**61**	1-hour x 2	**122 h**

FEDERAL COST: The estimated annual cost to the Federal government is: no additional cost other that the personnel cost of staff under normal duties and responsibilities.

If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:

The selection of your targeted respondents
1. Do you have a customer list or something similar that defines the universe of potential respondents and do you have a sampling plan for selecting from this universe?
[x] Yes [ ] No

If Yes: Please provide a description of both below (or attach the sampling plan)

If No: Please provide a description of how you plan to identify your potential group of respondents and how you will select them or ask them to self-select/volunteer

The survey will be administered semi-annually if programmatic shortages of Rifampin (RIF), are identified **and** if it is considered to be in the best interests of tuberculosis programs across the country that CDC systematically gather information to understand the extent of the problem regionally or nationally. The universe of potential respondents will consist of either the Tuberculosis Program Manager or Tuberculosis Controller from each of the 61 jurisdictions funded under the Notice of Funding Opportunity CDC-RFA-PS20-2001, **Tuberculosis Elimination and Laboratory Cooperative Agreement,** National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Division of TB Elimination. These are 50 state, 9 big-city (Chicago, NYC, Houston, Los Angeles, San Francisco, San Diego, Baltimore, Philadelphia, DC) and two territorial (Puerto Rico and US Virgin Islands) tuberculosis programs who use federal funds to support personnel, equipment, travel and contractual costs, with substantial involvement and consultation by CDC staff at the Division. The sampling plan will be to include all 61 jurisdictions when inquiring, as the intent is to understand the extent and loci of the problem when identified, rather than to attempt to gather some representative sample of responses.

Administration of the Instrument

1. How will you collect the information? (Check all that apply)
   - [ ] Web-based or other forms of Social Media
   - [ ] Telephone
   - [ ] In-person
   - [ ] Mail
   - [x] Other, Explain: An assessment will be emailed to each correspondent by Division staff who provide daily guidance to the state and local programs as part of their normal duties (project officers).
2. Will interviewers or facilitators be used? [ ] Yes [x] No

Please make sure that all instruments, instructions, and scripts are submitted with the request.