Import Trade Auxiliary Communication System

OMB Control No. 0910-NEW

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

FDA is requesting OMB approval to collect information via the Import Trade Auxiliary Communication System (ITACS) via a new ITACS account management function (also referred to herein as the ITACS "user account" function). The information that is collected consists of certain basic identifying information of the individual and firm who is applying to create the ITACS user account, such as the person's name, the firm's name, a contact email address, an account password, etc. This information collection request accounts for that collection of information. This is a new data collection, and FDA will implement the ITACS account management function upon approval by OMB of this ICR.

The authorizing statute for this collection is section 301 of the Public Health Service Act (24 U.S.C. 241).

FDA originally deployed ITACS in 2012 to improve communication between FDA and the import trade community. FDA expects the addition of the ITACS user account function to substantially improve import trade community members' experiences with ITACS and the process of importing FDA-regulated articles into the U.S.

ITACS user accounts provide members of the import trade community with secure access to ITACS. To create an ITACS user account, the member of the import trade community must submit certain basic information (such as the individual's name, the firm's name, a contact email address, an account password, etc.) to FDA. Once the ITACS user account is created, the ITACS user account enables FDA to distribute Notices of FDA Action to the user electronically via email (rather than regular mail), enables the user to download Notices of FDA Action from within ITACS, and allows the user to view in ITACS the details of specific information requests which are currently delivered via hard copy Notices of FDA Action. These functions require user accounts because the information may only be divulged to certain interested parties to an entry of imported goods. FDA will verify the identity of applicants prior to approving user account access. ITACS user account functionality will also allow for potential future ITACS enhancements, requested by the import trade community, that require, or would benefit from, secure access.

2. Purpose and Use of the Information Collection

Information collected from the import trade community will be used by FDA's Office of Regulatory Affairs, Division of Compliance Systems, to verify the identity of the applicant requesting the ITACS account. Once a user account is established, the user account holder is able to use their user account to securely access and use ITACS. ITACS user accounts enable FDA to distribute Notices of FDA Action to users electronically via email (rather than regular mail), enable users to download Notices of FDA Action from within ITACS, and allow users to view in ITACS the details of specific information requests which are currently delivered via hard copy Notices of FDA Action. Respondents to this collection of information include the private sector (primarily customs brokers, importers and consignees (i.e., owners or consignees of FDA-regulated articles offered for import).

3. Use of Improved Information Technology and Burden Reduction

All information will be collected electronically via use of a fillable form available through the existing FDA Unified Registration and Listing System (FURLS).

FDA estimates that 100% of the respondents will use electronic means to fulfill the agency's request.

4. Efforts to Identify Duplication and Use of Similar Information

If a firm already has an existing account within FDA's FURLS system, they will be allowed to add ITACS Account Management (also referred to herein as "ITACS user account") capability to that existing account if they choose. This will greatly help reduce duplication of similar information.

5. Impact on Small Businesses or Other Small Entities

We expect almost all (approximately 4800 of the 5000) respondents to be small businesses. However, we do not expect the collection of information to have an undue effect on small businesses. The amount and type of information collected is generally the same across all respondents, and FDA has limited the amount of information to be collected per respondent to only the minimum information necessary to create a user account in ITACS.

6. Consequences of Collecting the Information Less Frequently

The information will only need to be collected once from each respondent. If the data is not collected, FDA personnel would not be able to verify the identity of account applicants and guarantee security of accounts. Accounts would not be issued for those who have not supplied the information. Essentially, FDA would not be able to issue user accounts for ITACS if FDA were not able to collect this information.

There are no legal obstacles to reduce the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of 08/26/2016 (81 FR 58942). FDA received one comment.

The comment, in pertinent part, asks if those with ITACS user accounts will be able to create searchable reports of historical data. This is not a planned function at this time. We appreciate the suggestion and will consider it in the future as we continue to consider further expansions and improvements of ITACS Account Management functionality.

The comment also suggests that we add additional ITACS functions in the future, such as an ITACS function that explains why an entry reviewer has recommended detention and an ITACS function that notes receipt of USDA grading certification and allows for the certificate to be viewed within ITACS. The commenter states that the addition of such ITACS functions would benefit the import trade community. Although the suggestions for additional ITACS functions do not relate to the proposed ITACS user account function information collection, we appreciate the suggestions and we will consider them in the future as we continue to consider further expansions and improvements of ITACS functionality.

9. Explanation of Any Payment or Gift to Respondents

There are no payments or gifts provided to respondents for providing the information.

10. Assurance of Confidentiality Provided to Respondents

The information collected by this ICR is stored in FURLS, which is only accessible by designated FDA personnel and FDA contractors. Information will be kept private, as it will be handled in the same manner as other existing account information in FURLS.

The information associated with this ICR does not constitute a System of Records under the Privacy Act, as FDA does not use any personally identifiable information (PII) to retrieve any records from FURLS, including any records associated with this ICR. The PII collected by this ICR is used only for the purposes of facilitating each firm's access to its ITACS user account and to establish a point-of-contact associated with the firm to facilitate our ITACS-related communications with the firm.

11. Justification for Sensitive Questions

No information is required that may be considered of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

We have estimated that the reporting burden for this collection of information will be

2,250 hours in the first year and 250 hours annually after the first year.

We have estimated that there will be approximately 4,500 respondents to this collection of information in the first year and approximately 500 respondents to this collection of information thereafter. These estimates are based on the numbers (per FDA's Official Establishment Inventory (OEI)) of distinct filers (firms, who are customs brokers, who h have filed at least one FDA-regulated import entry) and distinct importers or consignees of FDA-regulated articles being offered for import who do not file FDA-regulated import entries themselves ("hereafter referred to as "importers or consignees"). There are approximately 4,900 distinct filers and approximately 40,000 distinct importers or consignees accounted for in FDA's OEI. Based on current ITACS use, we expect a substantial majority of the 4,900 filers (estimated at 75%, or 3,675 filers) to create user accounts in ITACS in the first year but only a very small amount of the 40,000 importers or consignees (estimated at about 3.3%, or 1325 importers or consignees,) to create ITACS user accounts in the first year. Because we expect a substantial majority of firms who will create an ITACS user account will create one in the first year the function is available, we expect much fewer firms per year to create user accounts after the first year. In accordance with these assumptions and estimates, we have roughly estimated that in the first year 5,000 filers, importers, or consignees will create ITACS user accounts and after the first year 500 filers, importers, or consignees (i.e., an estimated 1 10% of the number of respondents in the first year) will create ITACS user accounts per year. We ultimately expect the annual reporting burden to taper off further as more and more filers, importers, and consignees who want ITACS user accounts create them.

Each respondent will only respond to this collection of information once, i.e., when they create their user account.

We have determined that it will take 30 minutes on average for a respondent to set up a user account. This time estimate is based on the average amount of time it took to create a user account during FDA's ITACS user account User Acceptance Testing.

Accordingly, we have estimated the burden as follows:

Table 1.--Estimated First Year Reporting Burden

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Creation of ITACS account	4,500	1	4,500	0.5 (30 minutes)	2,250

Table 2.--Estimated Annual Reporting Burden					
Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Creation of ITACS account	500	1	500	0.5 (30 minutes)	250

Therefore, we estimate that the reporting burden in the first year will be 2,500 hours (2,250 hours + 250 hours) and the annual reporting burden thereafter will be 250 hours.

12b. Annualized Cost Burden Estimate

FDA estimates a $25 hourly wage for respondents, pursuant to the wage for "Brokerage Clerk" as published on the Department of Labor website, multiplied by 2 to account for benefits and overhead, for a total hourly wage of $50.

Table 3. Estimated One-Time Cost Burden			
Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Licensed Customs Broker	2,250	$50.00	$112,500

Table 4. Estimated Annual Recurring Cost Burden			
Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Licensed Customs Broker	250	$50.00	$12,500

Accordingly, we estimate the cost burden of the ITACS user account function to be $125,000 in the first year and $12,500 per year thereafter.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

Annualized cost to the federal government is expected to equal to the cost of approximately one FDA GS-13 Full Time Equivalent (FTE) to review and approve or reject account applications and to monitor the helpdesk for ITACS accounts, although we expect FDA management of user accounts to take more time in the first year and to ultimately taper off in subsequent years as accounts are approved and established. One GS-13 step 1 FDA FTE has an annual salary of $73,846.00, based on the 2016 General

Schedule (Base). Multiplied by 2 to account for benefits, locality adjustment, and overhead, makes for a total annual cost to the federal government of $147,692.

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Information collected will not be published, tabulated or manipulated.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA is not seeking approval to display the expiration date of OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.