DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2496]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Import Trade Auxiliary Communication System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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 (PRA).

DATES: Fax written comments on the collection of information by June 26, 2017.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910-New and title ''Import Trade Auxiliary Communication System.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794.

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.

Import Trade Auxiliary Communication System

OMB Control Number 0910—NEW

The Import Trade Auxiliary Communication System (ITACS) currently provides the import trade community with four functions: The ability to check the status of FDA-regulated entries and lines, the ability to submit entry documentation electronically, the ability to electronically submit the location of goods for those lines targeted for FDA physical examination, and the ability to check estimated laboratory analysis completion dates. No user login accounts are currently necessary to access these functions; all that is necessary is a valid customs entry number that has been successfully transmitted to FDA.

FDA has developed ITACS user account management functionality. Implementation of this functionality would allow members of the import trade community to create and manage secure user accounts in ITACS, which would 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. ITACS user account management functionality would also allow for potential future ITACS enhancements, requested by the import trade community, that require user authentication.

To create a secure user account for ITACS via the user account management function, a person would have to enter basic information such as the person's name, their employer's name, a contact email address, an account password, etc., into ITACS via the user account management function interface.

In the **Federal Register** of August 26, 2016 (81 FR 58942), FDA published a 60-day notice requesting public comment on the proposed collection of information. 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.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Creation of ITACS account	5,000	1	5,000	0.5 (30 minutes)	2,500

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: May 18, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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