

## DIVISION OF IMPORT OPERATIONS

### DIO ADVISORY # 5

#### TIME REPORTING FOR ENTRY REVIEWERS

Issue Date: September 26, 2016

**SUMMARY:** This DIO Advisory provides instructions for entry review time reporting in OASIS. These instructions should be adhered to by all entry reviewers and will be effective on October 1, 2016.

**TARGET AUDIENCE:** Import Operations Branch Directors, Import Program Managers, Import Supervisors and Entry Reviewers.

**BACKGROUND:** The lack of standardized guidance for reporting entry review PODS time has led to inconsistencies in time reporting, including: calculation of time to be recorded; calculation of the number of lines reviewed; and the frequency of reporting. These inconsistencies result in inaccurate estimates of time spent on entry review by commodity and Center, which affects entry review resources allocated in the workplan, which in turn affects Full Time Equivalent (FTE) calculations. Standardizing entry review time reporting will ensure that hours accurately reflect entry review time by Center and ensure appropriate resource allocation.

**INSTRUCTIONS:** On a daily basis entry reviewers should track their time spent reviewing entries for each General Product Indicator. This can be as simple as keeping a record in an administrative notebook or on a desk calendar. This real-time daily tracking is necessary to ensure accurate reporting when entering the time into OASIS on the Wednesday following the previous work week.

When tracking entry review time, include time spent conducting non-ABI and electronic entry review [any activities resulting in may proceeds (MPRO), document requests (DRQ), requests for field and label exams (FEX/LEX), sample collection requests (SAM), and detention recommendations (DTR/DER)]. Additionally, track time spent conducting activities related to admissibility decision on a line such as time spent researching, talking with or emailing brokers and/or importers, reviewing documents, following-up on documents requests, or making error corrections. Including this time will ensure that entry review time accounts for the entire initial admissibility decision<sup>1</sup>.

OASIS time reporting consists of a combination of the time tracked by the entry reviewer and a line count generated by an ORADSS report titled "Entry Review Activities by Center past 3 months" (See ORADSS Entry Review Report section below). Apply the number of hours tracked for the reporting week to each of the 8 GPI/PAC code combinations (Table 1) as appropriate.

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<sup>1</sup> General inquiries from filers, importers or the general public, which do not relate to an entry being processed, are not included in entry review time tracking. Report general import inquiries in FACTS under Operation Code 92 and PAC 88R833 (EEPS/OASIS COOP ACT (TRNG GVN TO FILER)).

Time is reported in OASIS on Wednesdays for the previous one week period of time (Monday at 12:00 AM until 11:59 PM on Sunday); in the event of a Wednesday holiday, time is reported on Thursday. Reporting in this manner will streamline data entry while still providing the necessary information to determine entry review resources by center.

### **OASIS Time Reporting for Entry Review**

1. Open OASIS.
2. Select “User Opts”
3. Select “Imports Investigations Time”

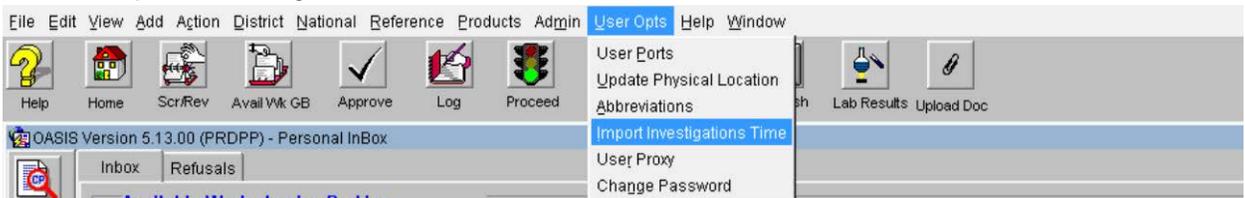


Figure 1: Accessing Import Investigations Time.

4. Complete the import investigations time screen as per the instructions below:

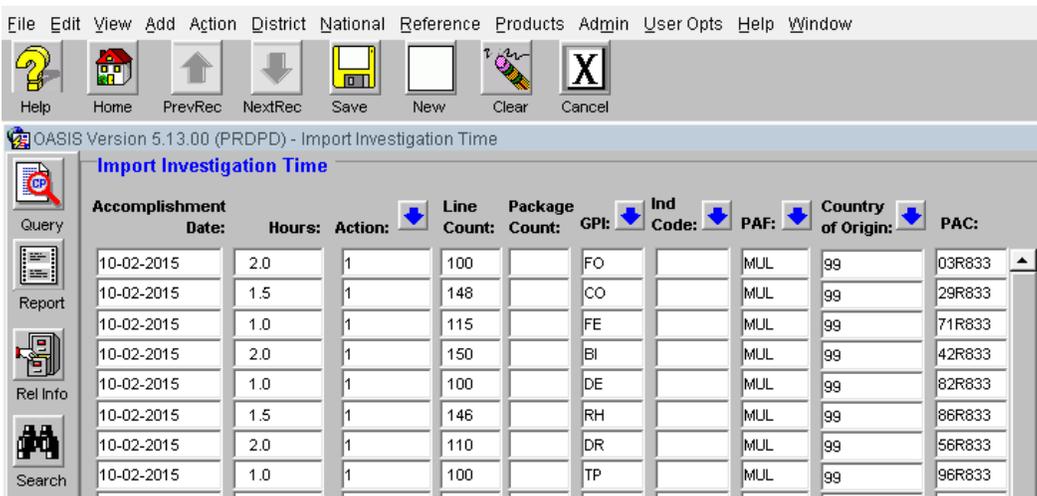


Figure 2: Imports Investigations Time Screen

Record all entry review time each week for the prior reporting period (Monday at 12:00 AM until 11:59 PM on Sunday)

- a. **Accomplishment Date**: Enter the last day of the time reporting period (i.e. Sunday of the previous week).
- b. **Hours**: Enter the time tracked during the previous reporting period to account for your entry review for the specific GPI.

**NOTE:** Time can be reported to one decimal place (0.1 is equal to 6 minutes and 0.5 is equal to 30 minutes).

- c. **Action**: Select Action Code 1 for Entry Review.
- d. **Line Count**: Enter the line count from the “Entry Review Activities by Center for past 3 months” ORADSS report for the specific GPI (See ORADSS Entry Review Report section below).

- i. The reviewer's line count in the report accounts for all lines reviewed each week (by GPI).
  - ii. **NOTE:** Do not report over 9,999 on the same reporting day. If the line count for the reporting week exceeds 9,999 lines, report the total on separate reporting days (e.g. Wednesday and Thursday). However, you will still enter the same accomplishment date.
- e. Package Count: Leave blank.
- f. GPI: Enter the appropriate GPI based on the information provided in Table 1.
- i. Use only the GPI and PAC codes found in Table 1 for entry review time reporting.
  - ii. **NOTE:** CFSAN and CDRH have two GPI/PAC combinations for reporting entry review time for their products. CDER, CBER, CVM, and CTP have one GPI/PAC combination for reporting entry review time for their products.
- g. Industry code: Leave blank.
- h. PAF: Select **MUL** for Multiple PAFs from the drop down list.
- i. Country of Origin: Select **99** for Multiple Countries from the drop down list.
- j. PAC: Enter the appropriate PAC based on the information provided in Table 1.
- i. **NOTE:** CFSAN and CDRH have two GPI/PAC combinations for reporting entry review time for their products. CDER, CBER, CVM, and CTP have one GPI/PAC combination for reporting entry review time for their products.

**Table 1:** GPI and PAC by Center.

<u>Center</u>	<u>GPI To Report</u>	<u>PAC To Report</u>
<b>CFSAN (Foods)</b> (Previously reported under GPIs: CA, VI, FR, FO, HW, FA, CA, IF)	<b>FO</b>	<b>03R833</b>
<b>CFSAN (Cosmetics)</b> (Previously reported under GPI codes: CO)	<b>CO</b>	<b>29R833</b>
<b>CVM (All)</b> (Previously reported under GPI codes: FE, AB, VI, FM, VD)	<b>FE</b>	<b>71R833</b>
<b>CBER (All)</b> (Previously reported under GPI code: BI)	<b>BI</b>	<b>42R833</b>
<b>CDRH (Medical Devices)</b> (Previously reported under GPI codes: DE, DI)	<b>DE</b>	<b>82R833</b>
<b>CDRH (Radiological Health)</b> (Previously reported under GPI code: RH)	<b>RH</b>	<b>86R833</b>
<b>CDER (All)</b> (Previously reported under GPI codes: AB, VI, DR)	<b>DR</b>	<b>56R833</b>
<b>CTP (All)</b> (Previously reported under GPI code: TP)	<b>TP</b>	<b>96R833</b>

### **ORADSS Entry Review Report**

Use the ORADSS report “Entry Review Activities by Center for past 3 months” to determine the lines reviewed for every entry reviewer broken down by GPI and PAC. This report provides the lines reviewed for the reporting week (Monday at 12:00 AM until 11:59 PM on Sunday). The lines reviewed will be required for time reporting in OASIS.

- To access the ORADSS Report, “Entry Review Activities by Center for past 3 months”, access the parent directory (<http://oradss.fda.gov:8085/reports/ora/>) where you will find the report titled “Entry Review Activities by Center for past 3 months”.
- To access the ORADSS Report directly use the following link:  
[http://oradss.fda.gov:8085/reports/ora/diop/Entry\\_Review\\_Activities\\_by\\_Center\\_for\\_Past\\_3\\_Months.xlsx](http://oradss.fda.gov:8085/reports/ora/diop/Entry_Review_Activities_by_Center_for_Past_3_Months.xlsx)

**DIO CONTACT:** Shelly Rios, DIO Program Development and Implementation Branch  
Brigitte Strelnik, DIO Program Development and Implementation Branch

John E. Verbeten, Branch Chief  
DIO Program Development and Implementation Branch