



The Honorable Greg Walden  
Chairman, Energy and Commerce Committee  
House of Representatives  
Washington, D.C. 20515

JUL 31 2018

Dear Chairman Walden:

Thank you for your letter of June 8, 2018, cosigned by eight of your colleagues, regarding the work of the Food and Drug Administration's (FDA or Agency) Office of Criminal Investigations (OCI) to combat the opioid crisis. We appreciate the opportunity to further engage with you on this important topic.

OCI establishes investigative priorities for each FDA Center, and priorities for Fiscal Year (FY) 2017 and FY 2018 are as follows:

- Center for Drug Evaluation and Research (CDER): [REDACTED]  
unapproved medical products, drug diversion, contaminated drugs or drug products  
[REDACTED]
- Center for Food Safety and Applied Nutrition (CFSAN): [REDACTED]  
[REDACTED]
- Center for Devices and Radiological Health (CDRH): [REDACTED]  
[REDACTED]
- Center for Tobacco Products (CTP): [REDACTED]  
[REDACTED]
- Center for Biologics Evaluation and Research (CBER): [REDACTED]  
[REDACTED]
- Center for Veterinary Medical (CVM): [REDACTED]  
[REDACTED]

In addition to information regarding OCI's investigative priorities, you also requested information regarding OCI's FY 2017 and FY 2018 port of entry (POE) cases related to foreign unapproved medical products (FUMP), tobacco products, cosmetic products, opioids, fentanyl, and kratom. Please note that, generally, a prerequisite for OCI involvement in a criminal investigation is an underlying Federal Food, Drug, and Cosmetic Act (FD&C Act) violation. However, many times a case is indicted to include charges under the FD&C Act, but the defendant(s) do not ultimately plead to the FD&C Act counts. Further, given that the work of OCI is dynamic in nature, the statistical information provided in this letter is current as of the time it was collected, on or about June 2018.

While some of OCI's investigations are conducted with state and/or local law enforcement, less than 10 percent of all OCI convictions in FY 2017 and FY 2018 were state or local convictions. Most of OCI's cases are prosecuted at the Federal level, however, OCI tracks judicial actions by individual arrests, guilty pleas, and convictions as opposed to prosecutions. That said, we believe the number of arrests, guilty pleas, and convictions demonstrates the overall prosecutorial interest in the criminal investigations being pursued by OCI.

Finally, information related to OCI's Asset Forfeiture Program is being provided in response to your questions about OCI's seizure and forfeiture activities.

**Figure 1. Overall total OCI POE related investigations opened during FY 2017 and thus far in FY 2018 (data collected on or about June 2018)**

<b>Field Office</b>	<b>FY 2017</b>	<b>FY 2018</b>
<b>Chicago Field Office</b>	24	13
<b>Kansas Field Office</b>	36	22
<b>Los Angeles Field Office</b>	30	21
<b>Metro Field Office</b>	49	20
<b>Miami Field Office</b>	126	52
<b>New York Field Office</b>	74	39
<b>TOTAL</b>	<b>339</b>	<b>167</b>

**Figure 2. Foreign Unapproved Medical Product (FUMP) OCI POE investigations opened during FY 2017 and thus far in FY 2018\* (data collected on or about June 2018)**

<b>Field Office</b>	<b>FY 2017</b>	<b>FY 2018</b>
<b>Chicago Field Office</b>	15	11
<b>Kansas Field Office</b>	28	19
<b>Los Angeles Field Office</b>	25	19
<b>Metro Field Office</b>	38	18
<b>Miami Field Office</b>	109	46
<b>New York Field Office</b>	54	33
<b>TOTAL</b>	<b>269</b>	<b>146</b>

<b>Judicial actions</b>	<b>FY 2017</b>	<b>FY 2018</b>
<b>Arrests</b>	102	91
<b>Guilty Pleas</b>	58	62
<b>Convictions</b>	78	73
<b>Convictions vacated or overturned</b>	0	1

	<b>FY 2017</b>	<b>FY 2018</b>
<b>OCI POE related asset forfeiture activities involving FUMP</b>	18 investigations/124 assets/\$18.8 million	6 investigations/27 assets/\$34.7 million

**Figure 3. Tobacco Product OCI POE investigations opened during FY 2017 and thus far in FY 2018 (data collected on or about June 2018)**

<b>Field Office</b>	<b>FY 2017</b>	<b>FY 2018</b>
<b>Chicago Field Office</b>	10	2
<b>Kansas Field Office</b>	6	4
<b>Los Angeles Field Office</b>	3	1
<b>Metro Field Office</b>	11	2
<b>Miami Field Office</b>	6	2
<b>New York Field Office</b>	18	5
<b>TOTAL</b>	<b>54</b>	<b>16</b>

<b>Judicial actions</b>	<b>FY 2017</b>	<b>FY 2018</b>
<b>Arrests</b>	6	1
<b>Guilty pleas</b>	3	4
<b>Convictions</b>	3	4
<b>Convictions vacated or overturned</b>	0	0

	<b>FY 2017</b>	<b>FY 2018</b>
<b>OCI POE related asset forfeiture activities involving tobacco products</b>	1 investigation/2 assets/\$300,000	None

**Figure 4. Cosmetic Products\*\*OCI POE Investigations opened during FY 2017 and thus far in FY 2018\* (data collected on or about June 2018)**

<b>Field Office</b>	<b>FY 2017</b>	<b>FY 2018</b>
<b>Chicago Field Office</b>	4	3
<b>Kansas City Field Office</b>	7	6
<b>Los Angeles Field Office</b>	9	9
<b>Metro Field Office</b>	1	5
<b>Miami Field Office</b>	59	16
<b>New York Field Office</b>	12	3
<b>TOTAL</b>	<b>92</b>	<b>42</b>

<b>Judicial Actions</b>	<b>FY 2017</b>	<b>FY 2018</b>
<b>Arrests</b>	6	12
<b>Guilty pleas</b>	6	5
<b>Convictions</b>	6	6
<b>Convictions vacated or overturned</b>	0	1

\*\*Please note that cosmetic products are regulated by CFSAN. Some human drug products regulated by CDER or medical devices regulated by CDRH are sometimes referred to as cosmetic products by certain external parties (i.e., Botox and dermal fillers). This chart includes Botox and dermal filler types of products. These types of products are already included in the tables detailing OCI's overall POE related activities and the one specifically addressing FUMP. Asset Forfeiture Program data has also been captured by information provided for other product areas. There are no asset forfeitures for cosmetics for this time period.

**Figure 5. Opioid Product OCI POE investigations opened during FY 2017 and thus far in FY 2018\* (data collected on or about June 2018)**

<b>Field Office</b>	<b>FY 2017</b>	<b>FY 2018</b>
<b>Chicago Field Office</b>	1	1
<b>Kansas Field Office</b>	2	4
<b>Los Angeles Field Office</b>	2	4
<b>Metro Field Office</b>	8	3
<b>Miami Field Office</b>	3	6
<b>New York Field Office</b>	3	7
<b>TOTAL</b>	<b>19</b>	<b>25</b>

<b>Judicial Actions</b>	<b>FY 2017</b>	<b>FY 2018</b>
<b>Arrests</b>	15	17
<b>Guilty Pleas</b>	4	5
<b>Convictions</b>	4	9
<b>Convictions vacated or overturned</b>	0	0

	<b>FY 2017</b>	<b>FY 2018</b>
<b>OCI POE related asset forfeiture activities involving opioid products</b>	None	2 investigations/9 assets/\$126,000

**Figure 6. Fentanyl OCI POE investigations opened during FY 2017  
and thus far in FY 2018\*  
(data collected on or about June 2018)**

<b>Field Office</b>	<b>FY 2017</b>	<b>FY 2018</b>
<b>Chicago Field Office</b>	1	0
<b>Kansas Field Office</b>	0	0
<b>Los Angeles Field Office</b>	0	0
<b>Metro Field Office</b>	2	1
<b>Miami Field Office</b>	1	3
<b>New York Field Office</b>	0	0
<b>TOTAL</b>	<b>4</b>	<b>4</b>

<b>Judicial Actions</b>	<b>FY 2017</b>	<b>FY 2018</b>
<b>Arrests</b>	0	9
<b>Guilty Pleas</b>	0	0
<b>Convictions</b>	0	0
<b>Convictions vacated or overturned</b>	0	0

	<b>FY 2017</b>	<b>FY 2018</b>
<b>OCI POE related asset forfeiture activities involving fentanyl products</b>	None	None

\*Please note the respective statistical breakdowns for foreign unapproved medical products, cosmetics, opioids, and fentanyl may reference the same criminal investigations.

**Figure 7. Kratom OCI POE investigations opened during FY 2017  
and thus far in FY 2018  
(data collected on or about June 2018)**

<b>Field Office</b>	<b>FY 2017</b>	<b>FY 2018</b>
<b>Chicago Field Office</b>	0	0
<b>Kansas Field Office</b>	0	1
<b>Los Angeles Field Office</b>	0	0
<b>Metro Field Office</b>	0	0
<b>Miami Field Office</b>	0	0
<b>New York Field Office</b>	0	0
<b>TOTAL</b>	<b>0</b>	<b>1</b>

<b>Judicial Actions</b>	<b>FY 2017</b>	<b>FY 2018</b>
<b>Arrests</b>	0	0
<b>Guilty Pleas</b>	0	0
<b>Convictions</b>	0	0
<b>Convictions vacated or overturned</b>	0	0

	<b>FY 2017</b>	<b>FY 2018</b>
<b>OCI POE related asset forfeiture activities involving kratom products</b>	None	None



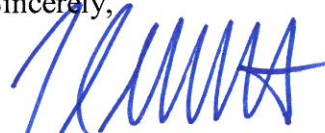
With regard to OCI POE staffing, the number of POE special agents doubled in August 2017 from six to 12. In 2017, OCI also added an Import Senior Operations Manager (SOM) to oversee the program, as well as four part-time POE special agents. This year, thanks to additional support in the FY18 Omnibus, OCI will be adding an additional 10 full-time POE special agent positions, which are pending a nationwide government-wide recruitment. Further, in FY 18 OCI also increased the number of part-time POE special agents to 10. The part-time POE special agents augment the full-time POEs during operational activities and further strengthen the presence of FDA at our domestic ports and mail hubs. Once fully staffed, the POE Program will consist of 22 full-time special agents, 10 part-time special agents, and two SOMs.

The priorities for the POE special agents remain to respond to relevant issues at the international mail facilities, ports, and express mail hubs, and to work collaboratively with Customs and Border Protection, and our other law enforcement counterparts to stop the flow of illicit medical products, tobacco, and food into the United States. Regarding FDA's coordination with other federal entities on opioid-related dark web cases, OCI is currently working with its Federal law enforcement partners, including Homeland Security Investigations, the Drug Enforcement Administration, the Internal Revenue Service Criminal Investigation division, and the Postal Inspection Service. OCI has also signed an agreement with member agencies of the National Intellectual Property Rights Coordination Center (IPR Center) to establish guidelines and procedures for the handling of leads received by the IPR Center, the coordination of investigative overlap, and the resolution of internal and field related conflicts resulting from IPR Center efforts.

Finally, with regard to the OCI director position, the vacancy announcement for recruiting a permanent OCI director posted on May 23, 2018, and closed June 22, 2018. FDA is working through the review and selection process with a goal of having a new director on board as quickly as possible. Recruiting the director remains ORA's top executive hiring priority.

Thank you for your interest in the important work of FDA-OCI. The same response has been sent to your cosigners.

Sincerely,



John Martin  
Principal Associate Commissioner  
for Legislative Affairs