

The Department of Justice Office of the Inspector General (OIG) today released a review of the Drug Enforcement Administration's (DEA) process to adjudicate administrative actions against businesses and professionals that register with the DEA to handle controlled substances. The OIG report found that the DEA's adjudicative process comports with applicable laws and regulations but the overall time it takes the DEA to adjudicate registrant actions is very lengthy. We also found that DEA generally does not have timeliness standards in place and, where it does, the agency consistently failed to meet them.

The *Controlled Substances Act of 1970* requires registration with the DEA by businesses that import, export, manufacture, or distribute controlled substances; health care practitioners entitled to dispense, administer, or prescribe controlled pharmaceuticals; and pharmacies entitled to fill prescriptions. If the DEA finds that a registrant or applicant has violated the law, it may issue an order to show cause why registration should not be revoked, suspended, or denied. If the violation poses an imminent threat to public health or safety, the DEA may issue an immediate suspension order, which deprives the registrant of the right to deal in controlled substances immediately. Orders to show cause and immediate suspension orders are collectively known as "registrant actions." After receiving notice of a registrant action, the registrant may either allow the DEA Administrator to issue a final decision or request a hearing. If the registrant requests a hearing, a DEA Administrative Law Judge (ALJ) will issue a recommended decision to the Administrator. The Administrator then is responsible for issuing a final decision by adopting, modifying, or rejecting the ALJ's recommended decision.

The OIG's review found that from 2008 through 2012, the time it took the DEA to reach a final adjudication of registrant actions was very lengthy. For example, the average time for the DEA to issue a final decision for immediate suspension orders ranged from 647 days in 2008 to 459 days in 2012, substantially above the DEA's 180-day goal for such adjudications. For all registrant actions – including both orders to show cause and immediate suspension orders – the average number of days the DEA took to make a final decision ranged from a high of 730 days in 2009 to 366 days in 2012. We also found that DEA does not have timeliness standards except for a 180-day goal for immediate suspension orders, and it consistently has failed to meet that internal standard. Delays in the adjudication process can create risks to public health and safety, for example, by allowing noncompliant registrants to operate their business or practice while the registrant action is being adjudicated, and can also affect the livelihoods of registrants capable of demonstrating their compliance.

The review identified several factors that may affect the timeliness of final decisions, including the lack of timeliness standards for all kinds of registrant actions, variations in how ALJs manage their caseloads, and a lack of guidance for DEA attorneys on preparing and submitting case summaries and related materials to the Office of the Administrator for adjudications made solely by the Administrator. We also found that the DEA has never analyzed the timeliness of its adjudication of registrant actions, and that due to its system for tracking adjudications, the DEA cannot effectively determine the time it takes to adjudicate each registrant action through final decision. The OIG's review did not assess the substantive bases for the DEA's decisions. However, the DEA has recently undertaken efforts to improve timeliness and to facilitate the adjudication of registrant actions.

The OIG made three recommendations to improve the DEA's ability to effectively and efficiently adjudicate all registrant actions in a timely manner and mitigate the potential adverse effects of

delays on the public, registrants, and the DEA. The DEA concurred with all three recommendations.

The report released today can be found on the OIG's website at: <http://www.justice.gov/oig/reports/2014/e1403.pdf>.