Report in Brief
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U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

The Food and Drug Administration Needs To Improve the Premarket Tobacco Application Review Process for Electronic Nicotine Delivery Systems To Protect Public Health

Why OIG Did This Audit

Use of e-cigarettes by youth remains a public health issue that is affecting children, families, schools, and communities. In July of 2019, a U.S. District court issued an order directing the Food and Drug Administration (FDA) to require that premarket tobacco product applications (PMTAs) be submitted for all new deemed tobacco products; otherwise, they are subject to the FDA's enforcement actions. By the September 9, 2020, deadline, FDA's Center for Tobacco Products (CTP) received PMTAs for more than 6 million electronic nicotine delivery systems (ENDS) products.

Our objectives were to determine (1) FDA's progress on reviewing applications for ENDS products; (2) whether FDA followed Federal statutes, regulations, policies, and guidance when granting or denying ENDS products; and (3) what actions FDA has taken to ensure that ENDS products that are not appropriate for the protection of public health are kept off the market.

How OIG Did This Audit

Our audit covered the PMTAs submitted to CTP from August 1, 2019, through September 9, 2020. To accomplish our audit objectives, we reviewed applicable Federal and program requirements, interviewed CTP officials, and reviewed the submission documents and CTP work products of a judgmental sample of ENDS products for which a PMTA was submitted.

What OIG Found

FDA's CTP made progress in reviewing PMTAs for ENDS products submitted by September 9, 2020. However, CTP was unable to complete a review of all the submitted PMTAs within the 1-year period during which, in accordance with a court order, products with applications filed in a timely manner might remain on the market pending CTP review. As of October 19, 2022, CTP had yet to decide on 53,128 of nearly 6.7 million ENDS products for which it received an application during the audit period.

CTP generally followed Federal statutes, regulations, policies and procedures, and guidance when granting or denying marketing orders for ENDS products; however, for the 15 products OIG reviewed that received a marketing-granted order, CTP did not issue an order within the 180 days. Even though CTP had outlined a timeline to meet the 180-day deadline, it encountered delays and was unable to comply.

CTP conducted enforcement actions, such as sending warning letters and seeking injunctions, to ensure that ENDS products that were not appropriate for the protection of public health were not marketed. As of October 2022, more than 440 warning letters had been issued to firms marketing illegal e-cigarettes containing tobacco-derived nicotine. Additionally, the Department of Justice, on FDA's behalf, filed the first complaints for permanent injunctions in Federal district courts against six e-cigarette manufacturers that failed to submit PMTA's for their products.

What OIG Recommends and FDA Comments

We recommend that CTP work with the Office of Personnel Management (OPM) to obtain direct-hire authority to assist CTP in reaching its full-time equivalent personnel goal and assess the PMTA review process and develop an action plan to resolve the backlog of PMTA applications and achieve compliance with the 180-day statutory timeline.

In written comments on our draft report and commenting on behalf of CTP, FDA concurred with the two recommendations and described actions it has taken or plans to take to address the findings. FDA stated that HHS, on behalf of CTP, submitted a new request to OPM for direct hire authority and CTP has begun work on an action plan to resolve the backlog of PMTA applications.