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

The Food and Drug Administration Generally Spent Prescription Drug User Fee Collections Appropriately

Why OIG Did This Review

The Prescription Drug User Fee Act of 1992, P.L. No. 102-571, authorized the Food and Drug Administration (FDA) to collect user fees from pharmaceutical and biotechnology companies seeking FDA approval of certain human drug and biological products to expedite the review of human drug applications. Congress must reauthorize the PDUFA every 5 years; it was renewed in 1997, 2002, 2007, 2012, and 2017. FDA expects to use the user fees it collects under the PDUFA to meet its goals for the timely review of human drug applications. We performed this audit to determine whether FDA appropriately expended prescription drug user fee collections.

Our objective was to determine whether FDA appropriately expended prescription drug user fee collections.

How OIG Did This Review

We obtained and reviewed documentation from the FDA to determine whether FDA appropriately spent prescription drug user fees.

We limited our review to $796,065,980 in prescription drug user fees reported for October 1, 2014, through September 30, 2015.

What OIG Found

FDA generally spent prescription drug user fee collections appropriately. However, FDA did not have adequate supporting documentation for $6,403 in travel expenses, made a duplicate payment for airfare of $1,213, and overpaid a traveler $587. FDA recovered the duplicate payment and overpayment from the travelers during our review. The lack of supporting documentation appeared to be an oversight by FDA staff and not a systemic issue. Accordingly, this report contains no recommendations.