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

The Food and Drug Administration Computed Prescription Drug User Fee Rates Accurately

Why OIG Did This Review

The Prescription Drug User Fee Act (PDUFA) of 1992, P.L. No. 102-571, authorized the Food and Drug Administration (FDA) to collect prescription drug 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 prescription drug 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 accurately computed prescription drug user fee rates.

Our objective was to determine whether FDA accurately computed prescription drug user fee rates.

How OIG Did This Review

We obtained and reviewed documentation from FDA, such as policies and procedures and financial records, to determine whether it accurately computed prescription drug user fee rates. We also analyzed prescription drug user fee collection amounts. We limited our review to $821.9 million in prescription drug user fee collections reported for October 1, 2014, through September 30, 2015.

What OIG Found

FDA computed prescription drug user fee rates accurately. We determined that the human drug review workload computation was appropriate. We also determined that the inflation adjustment for personnel compensation and benefits and nonpersonnel compensation and benefit costs were correctly computed.

Accordingly, this report contains no recommendations.