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FDA MEDICAL DEVICE REVIEWS

Evaluation is Needed to Assure Requests for Additional Information Follow a Least Burdensome Approach

GAO Highlights

Highlights of GAO-18-140, a report to congressional requestors

Why GAO Did This Study

Determining that a new medical device is safe and effective is a substantial investment of time and resources for the sponsor and FDA, the agency that regulates medical devices. FDA relies on the device sponsor to provide supporting data at the time of its original submission, and the agency can request additional information during the review. The Federal Food, Drug, and Cosmetic Act, as amended, requires that when FDA requests additional information from sponsors, the agency consider the least burdensome means of evaluating a medical device.

GAO was asked to provide information on FDA's implementation of the least burdensome requirements in its medical device review process. This report (1) describes FDA's requests for additional information and sponsor disagreements, (2) describes its least burdensome training efforts, and (3) describes FDA actions to improve its requests for additional information and examines the extent to which it has evaluated its implementation of the least burdensome requirements. GAO reviewed FDA documents and guidance and interviewed agency officials. GAO also interviewed officials from four relevant medical device manufacturing associations.

What GAO Recommends

GAO is making one recommendation that FDA develop and use performance metrics to evaluate the implementation of the least burdensome requirements. The Department of Health and Human Services agreed with GAO's recommendation.

View GAO-18-140. For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

What GAO Found

Since 1997, the Food and Drug Administration (FDA) has been required to consider the least burdensome means of evaluating certain types of medical devices for marketing, including when requesting that sponsors—generally manufacturers—seeking to market their medical devices provide information in addition to what was provided in their submissions. GAO found that, from 2001 through 2016, FDA issued letters asking sponsors to provide such information for a majority of the more than 62,000 medical device submissions that it reviewed. Sponsors may formally disagree with the request on the grounds that it is not the least burdensome method needed for FDA to review the submission. For example, sponsors appealed FDA decisions internally to agency management 63 times from 2013 through 2016, and of these, FDA identified 33 such appeals in which the sponsor raised an issue related to least burdensome requirements. FDA agreed or partially agreed with the sponsors in 11 of these appeals. Medical device industry representatives noted that these appeals may not fully represent the number of such disagreements, because applicants are generally concerned that an appeal would damage their relationship with FDA and potentially negatively affect future device applications.

FDA provided staff training that was specifically dedicated to addressing the least burdensome requirements from 1997 through 1999. Since 1999, FDA has not offered a course dedicated to the least burdensome requirements, but has incorporated related concepts into other training programs, such as in a training mandatory for most new reviewers. In response to the 21st Century Cures Act, enacted in 2016, FDA is providing new least burdensome training to all relevant employees, and said that 80 percent had received the training as of October 2, 2017. Although FDA did not specifically evaluate the effectiveness of past training on least burdensome requirements, it is implementing an evaluation of all device-related training, including the new least burdensome training. It also plans to complete a required audit of training on least burdensome requirements by June 2018.

FDA has not specifically evaluated implementation of the least burdensome requirements. However, in response to broader evaluations, such as an independent assessment of its medical device review process, the agency is in the early stages of developing processes that may improve its requests for additional information. For example, FDA plans to conduct an audit of letters requesting additional information. FDA is developing the audit's methodology and expects it will assess whether the agency's process was followed. However, due to their early stage, the extent to which these efforts will allow FDA to assess implementation of the least burdensome requirements is unclear. In 2002, FDA stated that it planned to periodically assess the implementation of the least burdensome principles, and federal internal control standards identify the importance of performance metrics for such assessments. However, the agency has yet to develop performance metrics to do so. Until such measures are developed and used, FDA will not be able to evaluate whether it effectively and consistently applies a least burdensome approach in its medical device reviews.