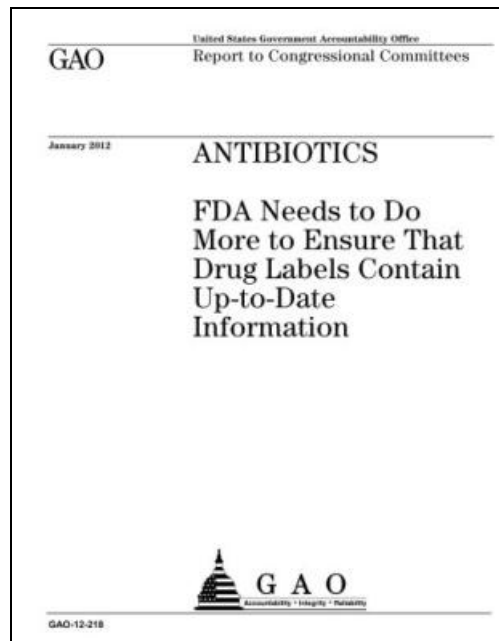


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Createspace Independent Publishing Platform, 2017. Paperback. Condition: New. Language: English . Brand New Book \*\*\*\*\* Print on Demand \*\*\*\*\*. Why GAO Did This Study Antibiotics are critical drugs that have saved millions of lives. Growing bacterial resistance to existing drugs and the fact that few new drugs are in development are public health concerns. The Food and Drug Administration Amendments Act of 2007 (FDAAA) required the Food and Drug Administration (FDA), an agency within the Department of Health and Human Services (HHS), to identify, periodically update, and make publicly available up-to-date breakpoints, the concentrations at which bacteria are categorized as susceptible to an antibiotic. Breakpoints are a required part of an antibiotic s label and are used by providers to determine appropriate treatments. FDAAA provided a financial incentive for antibiotic innovation and required FDA to hold a public meeting on antibiotic incentives and innovation. FDAAA directed GAO to report on the impact of these provisions on new drugs. This report (1) assesses FDA s efforts to help preserve antibiotic effectiveness by ensuring breakpoints on labels are up to date and (2) examines the impact of the antibiotic innovation provisions. GAO examined FDA data, guidance, and other documents; interviewed FDA officials; and obtained information from drug sponsors, such as manufacturers, that market antibiotics. What GAO Recommends GAO recommends that the Commissioner of FDA take steps to help ensure antibiotic labels contain up-to-date information, such as by.

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