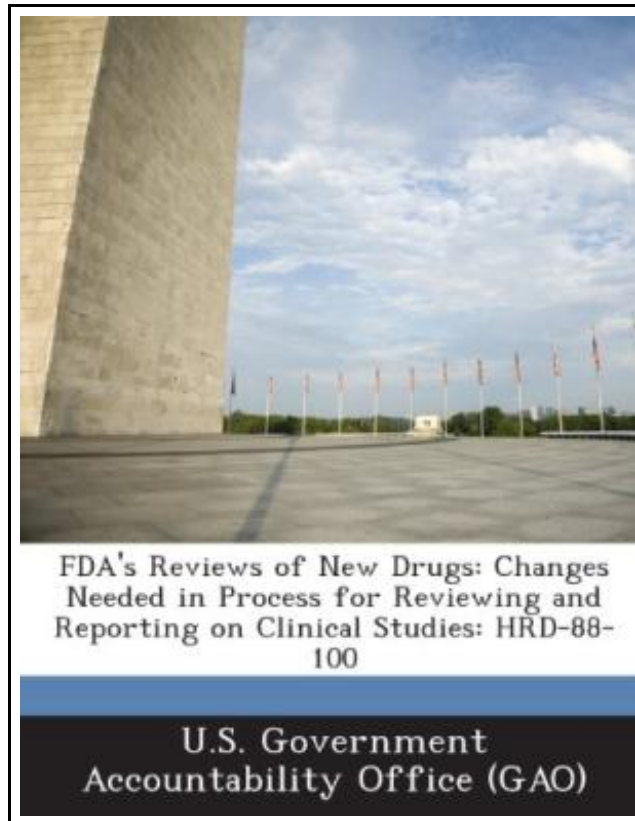


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Bibliogov. Paperback. Book Condition: New. This item is printed on demand. Paperback. 42 pages. Dimensions: 9.7in. x 7.4in. x 0.1in. In response to a congressional request, GAO reviewed the Food and Drug Administrations (FDA) Division of Scientific Investigations (DSI) activities, specifically: (1) its responsibilities relating to the approval of new drug and biological products; (2) the accuracy of FDA data and adequacy of oversight of clinical investigators, review boards, and laboratories involved in studies supporting new drug applications (NDA); and (3) the adequacy and timeliness of for-cause inspections. GAO found that: (1) the FDA database of information on review boards and laboratories was adequate and complete for use in scheduling inspections; (2) FDA increased its database maintenance staff and changed its regulations for easier investigator identification to eliminate a 9-month backlog and make the database more reliable; and (3) FDA revised its policy manual to assign joint responsibility for selecting studies for review to the drug review divisions and DSI. GAO also found that: (1) DSI conducted over 400 for-cause investigations of clinical investigators over the past 10 years usually due to indications of wrongdoing, unusually large numbers of investigations, or the importance of a study to a new drug application; (2) although DSI participation was necessary to maintain staff knowledge of particular drugs and improve interaction with drug review divisions, its participation had little effect on inspection results; (3) FDA completed only 88 of the 190 reviews scheduled within 12 months of receipt of NDA and did not notify its district offices of the need to make reviews until at least 1 year after receipt on almost 73 percent of the remainder; and (4) district involvement in other high priority work, such as product-tampering investigations, delayed timely completion of reviews. This item ships from La Vergne, TN. Paperback.

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