



FDAs Reviews of New Drugs: Changes Needed in Process for Reviewing and Reporting on Clinical Studies: Hrd-88-100

By -

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;...



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