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PASSE ET PRESENT MELANGES (2)



RareBooksClub. Paperback. Book Condition: New. This item is printed on demand. Paperback. 54 pages. Original publisher: Washington, D. C. : U. S. Government Accountability Office, 2006 OCLC Number: (OCoLC)77593544 Subject: Pharmaceutical industry -- Research -- United States. Excerpt: . . . review process takes two or more cycles, the total approval time includes the time spent during the review cycles, plus the additional time the sponsor uses to address the issues raised by FDA. Over the past several years, numerous industry analysts and FDA noted a FDA Response to decline in the submission of applications for NDAs overall, and for Concerns Over the 16 innovative drugs, such as NMEs. In light of this, in January 2003, FDA Number of Drugs launched a broad initiative to improve the development and availability of Developed 17 innovative medical products, including new drugs. As part of this initiative, FDA sought to reduce: (1) the number of drugs requiring more than one review cycle, (2) overall approval times, and (3) development costs. To help accomplish this, FDA sought to improve the development and review process by educating drug sponsors on the type and extent of scientific data that must be present in the NDAs initial submission. Noting the decline in the number of NDAs, in 2004 FDA proposed a second, more targeted, initiative - known as the critical path initiative - to form a 18 collaborative effort between government, industry, and academia. In doing so, FDA cited an urgent need for a new product development tool kit to enable researchers to more effectively translate basic research discoveries into safe and effective products. Such tools include better techniques of identifying safety problems as early as possible and better methods for demonstrating medical effectiveness; tools, which according to FDA, could help...

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