

Women s Health: Women Sufficiently Represented in New Drug Testing, But FDA Oversight Needs Improvement: Gao-01-754



Filesize: 2.85 MB

Reviews

This is an incredible ebook which i actually have ever go through. This can be for those who statte that there had not been a really worth reading. I am just quickly can get a delight of reading a published book.
(Ms. Colleen Ziemann V)

WOMEN S HEALTH: WOMEN SUFFICIENTLY REPRESENTED IN NEW DRUG TESTING, BUT FDA OVERSIGHT NEEDS IMPROVEMENT: GAO-01-754

[DOWNLOAD PDF](#)

To get **Women s Health: Women Sufficiently Represented in New Drug Testing, But FDA Oversight Needs Improvement: Gao-01-754** eBook, make sure you click the link beneath and download the file or have accessibility to additional information which might be in conjunction with **WOMEN S HEALTH: WOMEN SUFFICIENTLY REPRESENTED IN NEW DRUG TESTING, BUT FDA OVERSIGHT NEEDS IMPROVEMENT: GAO-01-754** book.

Bibliogov, United States, 2013. Paperback. Book Condition: New. 246 x 189 mm. Language: English . Brand New Book ***** Print on Demand *****.This report reviews the Food and Drug Administration s (FDA) inclusion of women in clinical drug trials. GAO found that women were a majority of the clinical trial participants in the new drug applications (NDA) it examined and that every NDA included enough women in the pivotal studies to be able to statistically demonstrate that the drug is effective in women. Although these findings are welcome, GAO also found three areas of concern. The first is the relatively small proportion of women in early small-scale safety studies. These early studies provide important information on drugs toxicity and safe dosing levels for later stages of clinical development, and many of the NDAs GAO examined found significant sex differences in a drug s pharmacokinetics, or how it is absorbed, distributed, metabolized, excreted, and concentrated in the bloodstream. Second, GAO is not confident that either NDA sponsors or FDA s reviewers took full advantage of the available data to learn more about the effects of the drug in women and to explore potential sex differences in dosing. This is because NDA summary documents are not required to include analyses of sex differences, and many of them do not. Third, FDA lacks appropriate management systems to monitor how many women are in clinical trials, to be certain that NDAs and investigational new drug applications (IND) annual reports comply with regulations for presenting outcome data by sex and tabulating the number of women included in ongoing trials, and to confirm that its medical officers have adequately addressed sex-related issues in their reviews. Although FDA has taken some promising initial steps to address these deficiencies, it is important that the agency finalize the pilot..

[Read Women s Health: Women Sufficiently Represented in New Drug Testing, But FDA Oversight Needs Improvement: Gao-01-754 Online](#)[Download PDF Women s Health: Women Sufficiently Represented in New Drug Testing, But FDA Oversight Needs Improvement: Gao-01-754](#)

See Also



[PDF] Dating Advice for Women: Women s Guide to Dating and Being Irresistible: 16 Ways to Make Him Crave You and Keep His Attention (Dating Tips, Dating Advice, How to Date Men)

Access the hyperlink beneath to get "Dating Advice for Women: Women s Guide to Dating and Being Irresistible: 16 Ways to Make Him Crave You and Keep His Attention (Dating Tips, Dating Advice, How to Date Men)" file.

[Save ePub »](#)



[PDF] Self Esteem for Women: 10 Principles for Building Self Confidence and How to Be Happy in Life (Free Living, Happy Life, Overcoming Fear, Beauty Secrets, Self Concept)

Access the hyperlink beneath to get "Self Esteem for Women: 10 Principles for Building Self Confidence and How to Be Happy in Life (Free Living, Happy Life, Overcoming Fear, Beauty Secrets, Self Concept)" file.

[Save ePub »](#)



[PDF] Kids Perfect Party Book ("Australian Women's Weekly")

Access the hyperlink beneath to get "Kids Perfect Party Book ("Australian Women's Weekly")" file.

[Save ePub »](#)



[PDF] The New Green Smoothie Diet Solution: Nature s Fast Lane to Peak Health

Access the hyperlink beneath to get "The New Green Smoothie Diet Solution: Nature s Fast Lane to Peak Health" file.

[Save ePub »](#)



[PDF] Games with Books : 28 of the Best Childrens Books and How to Use Them to Help Your Child Learn - From Preschool to Third Grade

Access the hyperlink beneath to get "Games with Books : 28 of the Best Childrens Books and How to Use Them to Help Your Child Learn - From Preschool to Third Grade" file.

[Save ePub »](#)



[PDF] Games with Books : Twenty-Eight of the Best Childrens Books and How to Use Them to Help Your Child Learn - from Preschool to Third Grade

Access the hyperlink beneath to get "Games with Books : Twenty-Eight of the Best Childrens Books and How to Use Them to Help Your Child Learn - from Preschool to Third Grade" file.

[Save ePub »](#)