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| <b>TRANSMITTAL OF ANNUAL REPORTS FOR DRUGS<br/>AND BIOLOGICS FOR HUMAN USE<br/>(21 CFR 314.81)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |  |  |                              | DATE SUBMITTED                                                                                       |                                                                                                                                                                                                                                                                                                                           | Form Approved: OMB No. 0910-0001<br>Expiration Date: December 31, 2017<br>See OMB Statement on Reverse Side.                                                                                                                                                                                 |       |      |       |      |  |    |  |
| <p><b>NOTE:</b> This report is required by law (21 USC 355; 21 CFR 314.81). Failure to report can result in withdrawal of approval of the New Drug or Biologics License Application.</p> <p style="text-align: center;"><b>INSTRUCTIONS</b></p> <p>Complete a transmittal for each application for which an annual report is being submitted. If submitting electronically, submit one copy of the form and annual report to FDA. If submitting in paper, submit two copies of the transmittal form along with two copies of the annual report to FDA.</p> <p>If any part of the annual report applies to more than one application, list in item 7 all other applications to which such parts apply.</p> |  |  |                              |                                                                                                      |                                                                                                                                                                                                                                                                                                                           | 1. Application Type                                                                                                                                                                                                                                                                          |       |      |       |      |  |    |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |  |  |                              |                                                                                                      |                                                                                                                                                                                                                                                                                                                           | 2. Application Number                                                                                                                                                                                                                                                                        |       |      |       |      |  |    |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |  |  |                              |                                                                                                      |                                                                                                                                                                                                                                                                                                                           | Report No. (For FDA Use Only) <table border="1" style="float: right; width: 150px;"> <tr> <td style="width: 25px; height: 20px;"></td> <td style="width: 25px; height: 20px;"></td> <td style="width: 25px; height: 20px;"></td> <td style="width: 25px; height: 20px;"></td> </tr> </table> |       |      |       |      |  |    |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |  |  |                              |                                                                                                      |                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                              |       |      |       |      |  |    |  |
| APPLICANT NOTE<br>Reference NDA and/or BLA numbers (entered on Approval/Amendment Copy) in any subsequent correspondence regarding report.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  |  |                              |                                                                                                      |                                                                                                                                                                                                                                                                                                                           | 3. TYPE OF REPORT (Check one)<br><input type="checkbox"/> ANNUAL <input type="checkbox"/> OTHER                                                                                                                                                                                              |       |      |       |      |  |    |  |
| 3. APPLICANT                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |  |  | 4. PHONE NUMBER<br>(       ) |                                                                                                      |                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                              |       |      |       |      |  |    |  |
| 6. DRUG/BIOLOGIC NAME                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |  |  |                              |                                                                                                      |                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                              |       |      |       |      |  |    |  |
| 7. OTHER NDA OR BLA NUMBERS (List all numbers if any part of report applies to more than one number.)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |  |  |                              |                                                                                                      |                                                                                                                                                                                                                                                                                                                           | 8. PERIOD COVERED BY REPORT                                                                                                                                                                                                                                                                  |       |      |       |      |  |    |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |  |  |                              |                                                                                                      |                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                              |       |      |       | FROM |  | TO |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |  |  |                              |                                                                                                      |                                                                                                                                                                                                                                                                                                                           | YEAR                                                                                                                                                                                                                                                                                         | MONTH | YEAR | MONTH |      |  |    |  |
| 9. <b>NDA REPORT INFORMATION REQUIRED (See § 314.81 for description)</b><br>(Enter type of information attached under "Identification." If you have nothing to report, enter None.)<br>(INFORMATION IN "9b" AND "9c" IS ALWAYS REQUIRED.)                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |  |  |                              |                                                                                                      |                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                              |       |      |       |      |  |    |  |
| TYPE OF INFORMATION                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |  |  |                              | IDENTIFICATION (Electronic file name or CDTO location or Volume No.(s) / Tab(s) / Page(s) of Report) |                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                              |       |      |       |      |  |    |  |
| a. SUMMARY OF SIGNIFICANT NEW INFORMATION                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |  |  |                              |                                                                                                      |                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                              |       |      |       |      |  |    |  |
| b. DISTRIBUTION DATA <input type="checkbox"/> Authorized <input type="checkbox"/> Generic Info                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |  |  |                              |                                                                                                      |                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                              |       |      |       |      |  |    |  |
| c. LABELING (Whether or not previously submitted)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  |  |                              |                                                                                                      |                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                              |       |      |       |      |  |    |  |
| d. CHEMISTRY/MANUFACTURING AND CONTROLS CHANGES <input type="checkbox"/> SUPAC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |  |  |                              |                                                                                                      |                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                              |       |      |       |      |  |    |  |
| e. NONCLINICAL LABORATORY STUDIES                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  |  |                              |                                                                                                      |                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                              |       |      |       |      |  |    |  |
| f. CLINICAL DATA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |  |  |                              |                                                                                                      |                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                              |       |      |       |      |  |    |  |
| g. STATUS REPORTS OF POSTMARKETING STUDY COMMITMENTS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |  |  |                              |                                                                                                      |                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                              |       |      |       |      |  |    |  |
| h. STATUS OF OTHER POSTMARKETING STUDIES (e.g., voluntary studies, CMC commitment studies, and product stability studies)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |  |  |                              |                                                                                                      |                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                              |       |      |       |      |  |    |  |
| i. LOG OF OUTSTANDING REGULATORY BUSINESS (Optional)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |  |  |                              |                                                                                                      |                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                              |       |      |       |      |  |    |  |
| 10. <b>BLA REPORT INFORMATION REQUIRED (See § 301.70 for description)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |  |  |                              |                                                                                                      |                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                              |       |      |       |      |  |    |  |
| TYPE OF INFORMATION                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |  |  |                              | CONTENTS (Check box)                                                                                 |                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                              |       |      |       |      |  |    |  |
| a. ANNUAL PROGRESS REPORTS OF POSTMARKETING STUDIES                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |  |  |                              | <input type="checkbox"/>                                                                             |                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                              |       |      |       |      |  |    |  |
| 11. TYPED NAME AND TITLE OF RESPONSIBLE OFFICIAL OR AGENT                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |  |  |                              |                                                                                                      | 13. SIGNATURE                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                              |       |      |       |      |  |    |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |  |  |                              |                                                                                                      |                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                              |       |      |       |      |  |    |  |
| 12. APPLICANT'S RETURN ADDRESS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |  |  |                              |                                                                                                      | <b>FDA USE ONLY</b><br>NDA OR BLA NUMBER<br><table border="1" style="width: 100%; height: 40px;"> <tr> <td style="width: 25px; height: 20px;"></td> <td style="width: 25px; height: 20px;"></td> <td style="width: 25px; height: 20px;"></td> <td style="width: 25px; height: 20px;"></td> </tr> </table> DATE OF RECEIPT |                                                                                                                                                                                                                                                                                              |       |      |       |      |  |    |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |  |  |                              |                                                                                                      |                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                              |       |      |       |      |  |    |  |
| Name of Sponsor / Applicant / Submitter                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |  |  |                              |                                                                                                      |                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                              |       |      |       |      |  |    |  |
| Address 1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |  |  |                              |                                                                                                      |                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                              |       |      |       |      |  |    |  |
| Address 2                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |  |  |                              |                                                                                                      |                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                              |       |      |       |      |  |    |  |
| City                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |  |  | State                        |                                                                                                      | ZIP or Postal Code                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                              |       |      |       |      |  |    |  |

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*Design, Execution, and Management of Medical Device Clinical Trials* Salah M. Abdel-aleem, 2009-08-19 An essential introduction to conducting the various stages of medical device clinical trials Clinical research continues to be one of the most vital components of pharmaceutical biostatistical and medical studies *Design Execution and Management of Medical Device Clinical Trials* provides a uniform methodology for conducting and managing clinical trials Written in a style that is accessible to readers from diverse educational and professional backgrounds this book provides an in depth and broad overview for successfully performing clinical tasks and activities Throughout the book practical examples compiled from both the author s and other researchers previous clinical trial experiences are discussed in a sequential manner as they occur in the study starting from the development of the clinical protocol and the selection of clinical sites and ending with the completion of the final clinical study report Next readers are guided through the development of important clinical documents including informed consent forms case report forms and study logs A careful review of the Food and Drug Administration FDA and International Conference on Harmonisation ICH regulations applicable to medical devices is also featured Additional coverage includes Qualification and selection of investigators Study monitoring visits Definitions and reporting procedures for adverse events The use of biostatistical methodology in clinical research including the use of biostatistics for sample size determination and study endpoints The roles and responsibilities of all members of a clinical research team The book concludes with an insightful discussion of special ethical conduct for human research and challenging issues to consider during the design of clinical studies A glossary lists important clinical and statistical terms used in clinical research and an extensive reference section provides additional resources for the most up to date literature on the topic *Design Execution and Management of Medical Device Clinical Trials* is an excellent book for clinical research or epidemiology courses at the upper undergraduate and graduate levels It is also an indispensable reference for clinical research associates clinical managers clinical scientists biostatisticians pharmacologists and any professional working in the field of clinical research who would like to better understand clinical research practices

**Women health women sufficiently represented in new drug testing, but FDA oversight needs improvement : report to congressional requesters , Agriculture, Rural Development, Food and Drug Administration, and Related Agencies**

**Appropriations for 2015** United States. Congress. House. Committee on Appropriations. Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, 2014 **Annual Report** United States. Food

Safety and Inspection Service. Office of Public Health Science, 2009 **Women's Health** United States. General Accounting

Office, 2001 Regulatory Aspects of Gene Therapy and Cell Therapy Products Maria Cristina Galli, Mercedes

Serabian, 2015-09-15 This book discusses the different regulatory pathways for gene therapy GT and cell therapy CT medicinal products implemented by national and international bodies throughout the world e g North and South America

Europe and Asia Each chapter authored by experts from various regulatory bodies throughout the international community walks the reader through the applications of nonclinical research to translational clinical research to licensure for these innovative products More specifically each chapter offers insights into fundamental considerations that are essential for developers of CT and GT products in the areas of product manufacturing pharmacology and toxicology and clinical trial design as well as pertinent must know guidelines and regulations Regulatory Aspects of Gene Therapy and Cell Therapy Products A Global Perspective is part of the American Society of Gene and Cell Therapy sub series of the highly successful Advances in Experimental Medicine and Biology series It is essential reading for graduate students clinicians and researchers interested in gene and cell therapy and the regulation of pharmaceuticals **Agriculture, Rural**

**Development, Food and Drug Administration, and Related Agencies Appropriations for 2017: USDA Food Safety and Inspection Service; USDA Food and Nutrition Service; USDA Rural Development; USDA Research, Education, and Economics** United States. Congress. House. Committee on Appropriations. Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies,2016 **107-2 Hearings: Agriculture, Rural**

**Development, Food and Drug Administration, Etc., Related Agencies Appropriations For 2003, Part 5, 2002, \***,2002 **Mann's Pharmacovigilance** Elizabeth B. Andrews,Nicholas Moore,2014-06-23 Highly Commended at the BMA Medical Book Awards 2015 Mann s Pharmacovigilance is the definitive reference for the science of detection assessment understanding and prevention of the adverse effects of medicines including vaccines and biologics Pharmacovigilance is increasingly important in improving drug safety for patients and reducing risk within the practice of pharmaceutical medicine This new third edition covers the regulatory basis and the practice of pharmacovigilance and spontaneous adverse event reporting throughout the world It examines signal detection and analysis including the use of population based databases and pharmacoepidemiological methodologies to proactively monitor for and assess safety signals It includes chapters on drug safety practice in specific organ classes special populations and special products and new developments in the field From an international team of expert editors and contributors Mann s Pharmacovigilance is a reference for everyone working within pharmaceutical companies contract research organisations and medicine regulatory agencies and for all researchers and students of pharmaceutical medicine The book has been renamed in honor of Professor Ronald Mann whose vision and leadership brought the first two editions into being and who dedicated his long career to improving the safety and safe use of medicines **Annual Report - Administrative Conference of the United States** Administrative Conference of the United States,1981

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## **Table of Contents Annual Report Template Fda**

1. Understanding the eBook Annual Report Template Fda
  - The Rise of Digital Reading Annual Report Template Fda
  - Advantages of eBooks Over Traditional Books
2. Identifying Annual Report Template Fda
  - Exploring Different Genres
  - Considering Fiction vs. Non-Fiction
  - Determining Your Reading Goals
3. Choosing the Right eBook Platform
  - Popular eBook Platforms
  - Features to Look for in an Annual Report Template Fda
  - User-Friendly Interface
4. Exploring eBook Recommendations from Annual Report Template Fda
  - Personalized Recommendations
  - Annual Report Template Fda User Reviews and Ratings
  - Annual Report Template Fda and Bestseller Lists
5. Accessing Annual Report Template Fda Free and Paid eBooks
  - Annual Report Template Fda Public Domain eBooks
  - Annual Report Template Fda eBook Subscription Services
  - Annual Report Template Fda Budget-Friendly Options
6. Navigating Annual Report Template Fda eBook Formats

- ePub, PDF, MOBI, and More
- Annual Report Template Fda Compatibility with Devices
- Annual Report Template Fda Enhanced eBook Features
- 7. Enhancing Your Reading Experience
  - Adjustable Fonts and Text Sizes of Annual Report Template Fda
  - Highlighting and Note-Taking Annual Report Template Fda
  - Interactive Elements Annual Report Template Fda
- 8. Staying Engaged with Annual Report Template Fda
  - Joining Online Reading Communities
  - Participating in Virtual Book Clubs
  - Following Authors and Publishers Annual Report Template Fda
- 9. Balancing eBooks and Physical Books Annual Report Template Fda
  - Benefits of a Digital Library
  - Creating a Diverse Reading Collection Annual Report Template Fda
- 10. Overcoming Reading Challenges
  - Dealing with Digital Eye Strain
  - Minimizing Distractions
  - Managing Screen Time
- 11. Cultivating a Reading Routine Annual Report Template Fda
  - Setting Reading Goals Annual Report Template Fda
  - Carving Out Dedicated Reading Time
- 12. Sourcing Reliable Information of Annual Report Template Fda
  - Fact-Checking eBook Content of Annual Report Template Fda
  - Distinguishing Credible Sources
- 13. Promoting Lifelong Learning
  - Utilizing eBooks for Skill Development
  - Exploring Educational eBooks
- 14. Embracing eBook Trends
  - Integration of Multimedia Elements
  - Interactive and Gamified eBooks

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