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International Journal of Pharmaceutics 210 (2000) 123–124

international journal of pharmaceutics

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Book review

***New Drug Approval Process' (3rd ed.)*, Edited by Richard Guarino, pp xxiii +471, Dekker, New York, 2000. ISBN 0-8247-0308-1**

The first edition of this book was published in 1987, a revised edition was published in 1992, and this third edition is now completely reorganised and updated. It is one of over 100 books in the series 'Drugs and the Pharmaceutical Sciences'; whose Executive Editor is James Swarbrick.

The book deals with clinical trial and registration filings to the US Food and Drug Administration, how this information is to be gathered together, and how it is to be presented to the agency as Investigational New Drug applications (INDs) and New Drug Applications (NDAs). It is organised into five key sections with chapters by individual contributors in each section. Part I deals with 'Regulatory Aspects of New Drug Development', Part 11 with 'Clinical Research Development', Part III with 'Good Clinical Practices', Part IV with 'The Orphan Drug and the Rx to OTC Switch', and Part V with 'Effective Methodology in Expediting NDA Approval'.

Contributors who work for consultancy companies and both small and large pharmaceutical companies have written the individual chapters. Thus they bring a wide experience to their tasks. Richard Guarino himself has written or co-written three of the chapters, one on NDA requirements, one on Clinical Research Protocols and one on Adverse Drug Reactions. The chapter on 'Clinical development, regulations and trends for OTC drugs' is written by William Gilbertson of CDER, and Steven Francesco of Francesco International.

Some information on the review process within FDA is included in the chapter 'Industry and FDA Liaison' by William Troetel, and he includes information on CDER and the Advisory Committees, but it would have been useful to have more details.

Most of the references in the book are to the Code of Federal Regulations (CFR), and FDA's own guidance documents, and this is probably appropriate, but it is perhaps surprising when so much of the registration file is now covered by International Conference on Harmonisation (ICH) guidelines, that there are only six references to ICH.

The book would be a useful introduction for anyone starting work in a technical group in a pharmaceutical company, a Contract Research Organisation or a consultancy company into what is needed for an IND or an NDA, and the methodology of collecting the information. It would also be a useful background text for students at regulatory affairs courses. However it would need to be supplemented by reference to the current FDA and ICH guidelines and procedures (most of the references in the text date from 1998 or earlier).

As the subtitle of the book 'The Global Challenge' hints, the real challenge for pharmaceutical companies today is to design a development programme and produce documentation and reports for their major new products which can be used to construct registration files for all of the major agencies around the world. This is the objective of the Common Technical Document (CTD) and electronic CTD (e-CTD) programmes within ICH, now nearing fruition. But until this is

PII: S0378-5173(00)00566-4

achieved, there is still a need for guidance such as this on filing for registration in the US.

15 July 2210

24 August 2000

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