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Note generali	Includes index.
Nota di contenuto	Introduction - The FDA, Doctors and the Practice of Medicine -- Drugs -- Devices -- Biologics -- Combination Products -- Supplements and Neutraceuticals -- Foods -- Cosmetics and Cosmeceuticals -- The FDA (history, organization, budgets) -- The Approval Process (including Phases 1-4, advisory committees, Guidances and personal medicine) -- The FDA and Promotion and Advertising -- The FDA and Drug Names -- The FDA , Politics and the Public.
Sommario/riassunto	This book explains the Food and Drug Administration (FDA) as an institution and provides understanding of its nomenclature, societal role, policies, goals and challenges. While many readers will have some knowledge of the FDA, few have an appreciation of the many specific areas of FDA authority. For example, how many realize that the US is one of only two countries which allow direct-to-consumer drug advertising, which is regulated by FDA? Or that FDA itself advertises to try to prevent young people from smoking cigarettes, and that all proprietary drug names must be approved by FDA? How many doctors or other readers are familiar with the formal definition distinguishing drugs from devices and the importance this has for development costs

and for our knowledge about the ultimate products? How many know how much nutritional supplements are regulated by FDA? The FDA for Doctors is not for those looking for detailed instruction on dealing with the FDA or its operations. Rather, it is written by a doctor with doctors in mind, with the hope that the information in this book will make physicians, and other readers, more thoughtful and insightful, especially with regards to therapeutics and the many broad societal issues underlying FDA's activities. With over 40 years of experience as a clinical investigator in many trials done for FDA registration, the author has been a member of and chaired an FDA advisory committee, and has been a consultant to several divisions of the FDA. He has also had the opportunity to serve on the U.S. Senate Labor Committee, helping with its FDA oversight activities. In addition to a long academic medical career the author has been a consultant to and a full time employee of drug and device companies. .
