



FDA-Speak: A Glossary and Agency Guide

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Often thought of as a subdialect of American "governmentese," FDA-Speak is a language unique to healthcare regulators and those regulated. If you have any involvement with the US Food and Drug Administration, or if they have involvement with you, you need to speak the language. This revised and updated edition of FDA-Speak retains the original easy-to-use glossary format, but now includes more than three times the number of entries in the first edition, defining more than 2,500 acronyms and technical/regulatory words to which the FDA has applied its own distinctive meaning. FDA-Speak provides the definitive listing of all of the regulatory words, phrases, and acronyms important to development, manufacture, quality control, marketing, import/export, and registration of pharmaceuticals, diagnostic products, medical devices, software, veterinary products, biologics, nutrition and dietary supplements, and bulk chemicals. Don't miss the all-new section of appendices that will guide you to information you need on the FDA website.

Appendices include:

Laws Enforced by the FDA; FDA Organization Charts and Contact Information; FDA Field Operations Index and Inspection Guides; FDA Forms; FDA Guidance Documents; DSMA Staff Directory.

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