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### Drug submissions: Procedures to reach regulatory approval ...

Regulatory submissions begin in preclinical development, years before an investigational drug is given to a human subject. They are not only common throughout clinical development but—should the investigational drug become a marketed product—can continue as long as the product remains on the market.

### FDA Regulatory Submissions: A Primer

9780470371381 Guidebook for drug regulatory submissions. Weinberg, Sandy. John Wiley & Sons 2009 379 pages \$100.00 Hardcover KF3885 Weinberg (health care management. Clayton State U., Atlanta) is a former regulatory affairs and quality assurance executive at a pharmaceutical company; he has 30 years of experience in drug regulatory affairs and has written 12 books.

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