FDA Jurisdiction: A Matter of Definitions

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Description
This chapter, new in the third edition, concerns how Congress, the Food and Drug Administration, and the courts have treated the definitions of "food," "drug," "cosmetic," "device," and "human biological product." The scope of FDA's power is delineated almost entirely by the list of product categories over which it has jurisdiction. As the materials in this chapter show, the product definitions are strikingly broad and thus confer jurisdiction over a vast range of goods. Furthermore, the definitions are remarkably plastic, providing FDA with great flexibility to decide whether and how to regulate products. Sometimes FDA has interpreted the definitions expansively, so as to expand its power. On other occasions, the agency has construed the definitions narrowly, so as to avoid taking responsibility for products it does not want to regulate or to minimize the burdensomeness of the requirements it does impose.

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