
21 U.S. Code § 379j-71

Definitions

In this subpart:

- (1) The term “affiliate” means a business entity that has a relationship with a second business entity if, directly or indirectly—
 - (A) one business entity controls, or has the power to control, the other business entity; or
 - (B) a third party controls, or has power to control, both of the business entities.
- (2) The term “contract manufacturing organization facility” means an OTC monograph drug facility where neither the owner of such manufacturing facility nor any affiliate of such owner or facility sells the OTC monograph drug produced at such facility directly to wholesalers, retailers, or consumers in the United States.
- (3) The term “costs of resources allocated for OTC monograph drug activities” means the expenses in connection with OTC monograph drug activities for—
 - (A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees, and costs related to such officers, employees, and committees and costs related to contracts with such contractors;
 - (B) management of information, and the acquisition, maintenance, and repair of computer resources;
 - (C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and
 - (D) collecting fees under section 379j-72 of this title and accounting for resources allocated for OTC monograph drug activities.

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