

# 42 C.F.R. § 403.1201

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## Definitions.

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For the purposes of this subpart, the following definitions apply:

- (a) *Biological product*. Biological product means any biological product, as that term is defined in Public Health Service Act (“PHS Act”) section 351(i), that is licensed by the Food and Drug Administration pursuant to section 351 and is subject to the requirements of Federal Food, Drug, and Cosmetic Act (FDCA) section 503(b)(1).

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