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Pharmaceutical Product Expiration Date

National Cancer Institute

Source

National Cancer Institute. *Pharmaceutical Product Expiration Date*. NCI Thesaurus. Code C42693.

As part of the CGMP regulations, the FDA requires that drug products bear an expiration date determined by appropriate stability testing (21 CFR 211.137 and 211.166), after which the product may not meet the appropriate regulatory agencies requirements.. The FDA defines an expiration date as "the date placed on the container/labels of a drug product designating the time during which a batch of the product is expected to remain within the approved shelf life specifications if stored under defined conditions, and after which it may not be used." Expiration dates are generally limited to no more than 3 years after production, but longer stability periods are allowed for some very stable materials.