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# 21 U.S. Code § 360bbb-0a

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## Investigational drugs for use by eligible patients

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### **(a) Definitions**

For purposes of this section—

(1) the term “eligible patient” means a patient—

(A) who has been diagnosed with a life-threatening disease or condition (as defined in section 312.81 of title 21, Code of Federal Regulations (or any successor regulations));

(B) who has exhausted approved treatment options and is unable to participate in a clinical trial involving the eligible investigational drug, as certified by a physician, who—

(i) is in good standing with the physician’s licensing organization or board; and

(ii) will not be compensated directly by the manufacturer for so certifying; and

(C) who has provided to the treating physician written informed consent regarding the eligible investigational drug, or, as applicable, on whose behalf a legally authorized representative of the patient has provided such consent;

(2) the term “eligible investigational drug” means an investigational drug (as such term is used in section 360bbb of this title)—

(A) for which a Phase 1 clinical trial has been completed;

(B) that has not been approved or licensed for any use under section 355 of this title or section 351 of the Public Health Service Act [42 U.S.C. 262];

(C)

(i) for which an application has been filed under section 355(b) of this title or section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)]; or

(ii) that is under investigation in a clinical trial that—

(I) is intended to form the primary basis of a claim of effectiveness in support of approval or licensure under section 355 of this title or section 351 of the Public Health Service Act [42 U.S.C. 262]; and

(II) is the subject of an active investigational new drug application under section 355(i) of this title or section 351(a)(3) of the Public Health Service Act [42 U.S.C. 262(a)(3)], as applicable; and

(D) the active development or production of which is ongoing and has not been discontinued by the manufacturer or placed on clinical hold under section 355(i) of this title; and

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