21 U.S. Code § 353d

Process to update labeling for certain generic drugs

(a) Definitions

For purposes of this section:

(1) The term "covered drug" means a drug approved under section 355(c) of this title—

(A) for which there are no unexpired patents included in the list under section 355(j)(7) of this title and no unexpired period of exclusivity;

(B) for which the approval of the application has been withdrawn for reasons other than safety or effectiveness; and

(C) for which—

(i)

(I) there is new scientific evidence available pertaining to new or existing conditions of use that is not reflected in the approved labeling;

(II) the approved labeling does not reflect current legal and regulatory requirements for content or format; or

(III) there is a relevant accepted use in clinical practice that is not reflected in the approved labeling; and

(ii) updating the approved labeling would benefit the public health.

(2) The term "period of exclusivity", with respect to a drug approved under section 355(c) of this title, means any period of exclusivity under clause (ii), (iii), or (iv) of section 355(c)(3)(E) of this title, clause (ii), (iii), or (iv) of section 355(j)(5)(F) of this title, or section 355a, 355f, or 360cc of this title.

(3) The term "generic version" means a drug approved under section 355(j) of this title whose reference listed drug is a covered drug.

(4) The term "relevant accepted use" means a use for a drug in clinical practice that is supported by scientific evidence that appears to the Secretary to meet the standards for approval under section 355 of this title.

(5) The term "selected drug" means a covered drug for which the Secretary has determined through the process under subsection (c) that the labeling should be changed.