
21 U.S. Code § 360n

Priority review to encourage treatments for tropical diseases

(a) Definitions

In this section:

(1) Priority review

The term “priority review”, with respect to a human drug application as defined in section 379g(1) of this title, means review and action by the Secretary on such application not later than 6 months after receipt by the Secretary of such application, as described in the Manual of Policies and Procedures of the Food and Drug Administration and goals identified in the letters described in section 101(c) of the Food and Drug Administration Amendments Act of 2007.

(2) Priority review voucher

The term “priority review voucher” means a voucher issued by the Secretary to the sponsor of a tropical disease product application that entitles the holder of such voucher to priority review of a single human drug application submitted under section 355(b)(1) of this title or section 262 of title 42 after the date of approval of the tropical disease product application.

(3) Tropical disease

The term “tropical disease” means any of the following:

- (A) Tuberculosis.
- (B) Malaria.
- (C) Blinding trachoma.
- (D) Buruli Ulcer.
- (E) Cholera.
- (F) Dengue/dengue haemorrhagic fever.
- (G) Dracunculiasis (guinea-worm disease).
- (H) Fascioliasis.
- (I) Human African trypanosomiasis.
- (J) Leishmaniasis.
- (K) Leprosy.
- (L) Lymphatic filariasis.
- (M) Onchocerciasis.
- (N) Schistosomiasis.
- (O) Soil transmitted helminthiasis.
- (P) Yaws.

(Q) Filovirus Diseases.

(R) Zika Virus Disease.

(S) Any other infectious disease for which there is no significant market in developed nations and that disproportionately affects poor and marginalized populations, designated by order of the Secretary.

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