

FDAAA Section 1102

Priority Review Vouchers

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Section 1102 Overview

- FDA Amendments Act (FDAAA) enacted on September 27, 2007
- FDAAA Section 1102 adds a new Section 524 to the FD&C Act
- Provides for the granting of a priority review voucher to sponsors of applications for certain tropical disease products

Two key components of this provision

- Receiving the voucher
- Redeeming the voucher

Receiving a Priority Review Voucher

Criteria for Receiving a Priority Review Voucher

- The application must be for prevention or treatment of a listed tropical disease
- The application must be submitted under section 505(b)(1) of the Act or section 351 of the PHS Act
- The application must be for a human drug application (defined in section 735(1) of the FD&C Act)

Criteria for Receiving a Priority Review Voucher (cont.)

- The application must qualify for a priority review
- The drug that is the subject of the application must contain no active ingredient (including any ester or salt of the active ingredient) that has been approved in any other application under section 505(b)(1) of the FD&C Act or section 351 of the PHS Act

Listed Tropical diseases

- Tuberculosis
- Malaria
- Blinding trachoma
- Buruli Ulcer
- Cholera
- Dengue/Dengue haemorrhagic fever
- Dracunculiasis (guinea worm disease)
- Fascioliasis
- Human African trypanosomiasis
- Leishmaniasis
- Leprosy
- Lymphatic filariasis
- Onchocerciasis
- Schistosomiasis
- Soil transmitted helminthiasis
- Yaws

Listed Tropical diseases (cont.)

- Any other infectious disease for which there is no significant market in developed nations and that disproportionately affects poor and marginalized populations, designated by regulation by the Secretary (section 524(a)(3))

Requesting a Voucher

- FDA encourages early communication prior to submission of the marketing application
- The sponsor of a tropical disease application should request a voucher at the time of submission of the application
- FDA cannot guarantee that an application will qualify for a voucher until the time of application approval

Granting a Voucher

- The determination to grant a tropical disease priority review voucher is made at the time of application approval
- The decision to grant a voucher will be communicated at the time of approval
- Sponsor that receives a tropical disease priority review voucher may transfer the voucher to another sponsor

Redeeming a Priority Review Voucher

Criteria for Use of a Priority Review Voucher

- Must be an application submitted under section 505(b)(1) of the FD&C Act or section 351 of the PHS Act
- After the voucher is granted, and at least one year prior to using the voucher, the sponsor planning to use a voucher must notify FDA of intent to use the voucher and the date on which the sponsor intends to submit the application

Criteria for Use of a Priority Review Voucher (cont.)

- Sponsor using the voucher must pay an extra user fee based on the average cost of a priority NDA/BLA review in the previous fiscal year

Frequently Asked Questions

What is a priority review?

- CDER: The product, if approved, would provide a safe and effective therapy where no satisfactory alternative therapy exists or would be a significant improvement compared to marketed products
- CBER: The product, if approved, would provide a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a life-threatening disease

What is a priority review? (cont.)

- FDA is committed to a goal to review and act on 90% of applications with priority review status no later than six months from submission

Are combination products eligible for a priority review voucher?

- Yes, but only if all active ingredients meet the FDAAA criteria
- If the product contains any active ingredient that has been previously approved by FDA, it is not eligible

Are 505(b)(2) NDAs eligible for priority review vouchers?

- Yes. FDAAA requires that an NDA must be submitted under section 505(b)(1) of the Act in order to be eligible for a voucher. 505(b)(2) NDAs are submitted under section 505(b)(1).

Can a priority review voucher be used for a 505(b)(2) NDA?

- Yes. FDAAA allows the use of a voucher for an NDA that is submitted under section 505(b)(1). 505(b)(2) NDAs are submitted under section 505(b)(1).

Does this provision of FDAAA apply to Orphan Drug development?

- A drug that qualifies for a tropical disease product application may also qualify for incentives under provisions of the Orphan Drug Act
- Potential sponsors should contact FDA Office of Orphan Products Development

Who should we contact for questions about a tropical disease application?

- Contact the review division that manages applications for the therapeutic class of interest
- You are encouraged to initiate contact at an early stage of development

Information Regarding this Meeting

www.fda.gov/cder/meeting/tropical_diseases_2008.htm