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Opportunity to Earn Transferable Priority Review Vouchers

The recently enacted Food and Drug Administration Amendments Act of 2007 adds new Section 524 to the Federal Food, Drug and Cosmetic Act designed to encourage the development of treatments for tropical diseases. The new section establishes a program under which FDA will issue transferable vouchers that may be redeemed to obtain priority review of a future application upon approval of a product for the treatment of a tropical disease.

A priority review voucher will be awarded to a sponsor upon approval of a "tropical disease product application." A "tropical disease product application" is a new chemical entity human drug application that is itself deemed eligible for priority review under the preexisting priority review criteria¹ and is approved for use in the prevention, detection, or treatment of a tropical disease. The term "tropical disease" includes the specific diseases listed in new Section 524,² as well as other infectious diseases designated by regulation.

All tropical disease product applications submitted and approved after the date of enactment of the FDAAA (*i.e.*, September 27, 2007) will earn a voucher. However, no vouchers will be issued until September 27, 2008.

A priority review voucher may be redeemed for priority six month review of one new drug application submitted under Section 505(b)(1) of the FDCA or one biologics license application submitted under Section 351 of the Public Health Services Act that would otherwise be reviewed under FDA's standard 10 month review clock. To redeem the voucher, the sponsor must also pay a special priority review user fee in addition to standard PDUFA user fees. The amount of this special fee will be established by FDA each fiscal year starting with FY2009 based on the average cost associated with priority review of an application during the previous fiscal year.

¹ In brief, applications for the approval of drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists are eligible for priority review. The designation is made in accordance with the procedures and considerations outlined in CDER's Manual of Policies and Procedures, 6020.3 (July 16, 2007), available at: <http://www.fda.gov/cder/mapp/6020.3R.pdf>.

² The statute lists: 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, and yaws.



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A sponsor must notify FDA of its intent to redeem a voucher at least one year prior to submission of the subject application, and must also inform the Agency of the date on which the sponsor intends to submit the application. This notification constitutes a binding commitment to pay the associated priority review user fee. Priority review vouchers are fully transferable.