



Fall 2012

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Recommended Citation

Trillis, Floyd III, "Where Are Your Drugs Really Made and Who is Regulating it?" (2012). *In the Balance*. 25. <https://engagedscholarship.csuohio.edu/inthebalance/25>

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Where Are Your Drugs Really Made and Who is Regulating it?

November 23, 2012

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Over the last decade, the pharmaceutical supply chain has become increasingly globalized. Up to 40% of all drugs Americans take are imported, and about 80% of the active ingredients in those drugs come from foreign sources.^[1] The U.S. FDA has struggled to conduct inspections of these foreign facilities, especially in emerging markets, due to a lack of appropriate resources and funding.^[2]

To address the growing number of regulatory challenges the FDA and representatives of the generic drug industry negotiated an agreement that ultimately passed into law on July 9, 2012 as the Generic Drug User Fee Amendment (GDUFA).^[3] The agreement marked the first time ever in which the FDA would receive funding from the generic drug industry.^[4] A portion of the money would be used to underwrite inspections of manufacturing facilities in foreign countries, which would be held every two years – the same frequency required for manufacturing facilities in the U.S.^[5]

Beginning on October 1, 2012, the annual funding from GDUFA user fees is set at \$229 million and will come from application fees (ANDAs and DMFs) as well as annual facility fees.^[6] The GDUFA fees will be imposed on both API and finished dose manufacturers which will ensure that all participants appropriately share the financial expense and benefits of the program. While the FDA has publicized information about the proposed user fee structure, the actual fee amounts will not be determined until months after GDUFA launches.^[7] Non-payment of annual facility fees from API and/or finished dose manufacturers will result in all products from those facilities being classified as misbranded and banned from sale in the U.S. market.^[8]

In a Commitment Letter that accompanied the legislation, the FDA vowed to review and act on 90% of original ANDAs within 10 months following the date of submission by year five of the program.^[9] This will reduce the overall expense of bringing a generic product to market, and deliver safe, effective, and affordable generic drugs to the public sooner.^[10] Most notably, the implementation of GDUFA will force generic drug manufacturers to accept responsibility for the relationships that they have with their foreign suppliers and for the products they put out to the market.^[11]

^[1] Gardiner Harris, *F.D.A. Confronts Challenge of Monitoring Imports*, N.Y. Times (June 20, 2011), http://www.nytimes.com/2011/06/21/health/policy/21food.html?_r=0.

[2] *See generally* Generic Drug User Fee Amendments of 2012, *GDUFA, a historic first: Providing user fees for FDA to ensure timely review of applications for generic drugs*, FDA (Oct. 25, 2012), <http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/default.htm>.

[3] *See generally* Generic Drug User Fee Amendments of 2012, *Fact Sheet: New User Fees for Generic Drugs Will Enhance Americans' Access to Less Expensive Drugs and Generate Major Cost Savings*, FDA (Aug. 17, 2012), <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCAAct/SignificantAmendmentsstotheFDCAAct/FDASIA/ucm310992.htm>.

[4] Alaric Dearment, *PDUFA, GDUFA make 2012 milestone year*, Drug Store News (Sept. 18, 2012), <http://drugstorenews.com/article/pdufa-gdufa-make-2012-milestone-year> [hereinafter Dearment].

[5] *See generally* Emerging Markets Outsourcing Report, *New FDA Inspection Fees Set to Benefit Contract Manufacturers in Emerging Markets*, PharmSource (last visited Oct. 28, 2012), http://www.pharmsource.com/images/pharmsource/PDFs/102011_EMOR_OCT11_PharmSource.pdf (according to 2009 figures, the FDA has inspected only 11% of the 3,765 foreign facilities in its database. However, it should be noted that some of the facilities in the database do not currently supply products to the U.S. market) [hereinafter Emerging Markets Outsourcing Report].

[6] *See generally* Generic Drug User Fee Amendments of 2012, *Guidance for Industry, Generic Drug User Fee Amendments of 2012: Questions and Answers*, FDA (Aug. 12, 2012), <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM316671.pdf> [hereinafter Guidance for Industry].

[7] *Id.* (under GDUFA, facilities, sites and organizations must first self-identify. Fees will be determined after the self-identification process has been completed, providing FDA information about the number of facilities that will be required to pay user fees).

[8] *Id.*

[9] *See* Dearment, *supra* note 4 (the current ANDA review time is 31 months at the FDA).

[10] *See* Guidance for Industry, *supra* note 6.

[11] *See* Emerging Markets Outsourcing Report, *supra* note 5.