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FDA Announces 2021 ADUFA and AGDUFA Fees

August 4, 2020

Animal Food and Drug

On Friday, FDA announced the Animal Drug User Fees (ADUFA fees) and Generic Animal Drug User Fees (AGDUFA fees)[1] for Fiscal Year 2021. The following table shows the 2021 rates, the 2020 rates, and the percent changes for each:

ADUFA Fees	FY 2021 Fee	FY 2020 Fee	Percent difference
New animal drug application	$574,810	$440,446	30.5% increase
Supplemental application[2]	$287,405	$220,223	30.5% increase
Product fee	$ 12,230	$ 11,353	7.7% increase
Establishment fee[3]	$166,695	$159,177	4.7% increase
Sponsor fee[4]	$142,881	$144,999	1.5% decrease

[1] FDA's announcement can be found here.

[2] The fee applies to a supplemental animal drug application for which safety or effectiveness data are required and animal drug applications subject to the criteria set forth in Section 512(d)(4) of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. § 360b(d)(4)).

[3] An animal drug establishment is subject to only one such fee per year.

[4] An animal drug sponsor is subject to only one such fee per year.

AGDUFA Fees	FY 2021 Fee	FY 2020 Fee	Percent difference
Abbreviated application	$513,423	$493,897	30.5% increase
Abbreviated combination application[5]	$256,712	$246,949	30.5% increase
Product fee	$ 17,235	$ 16,645	7.7% increase
Sponsor fee			
-Sponsor holds >6 approved abbreviated applications	$201,687	$172,329	17.04% increase
-Sponsor holds 2-6 approved abbreviated applications	$151,265	$129,247	17.04% increase
-Sponsor holds 0-1 approved abbreviated applications	$100,843	$ 86,165	17.03% increase

By December 31, 2020, FDA will issue invoices for FY 2021 product, establishment, and sponsor fees and payment will be due by January 31, 2021. The application fee rates are effective for applications submitted on or after October 1, 2020, and will remain in effect through September 30, 2021. FDA announced that it will not accept applications for review until FDA has received the full application fees and any other animal drug user fees the sponsor owes.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Animal Food and Drug practice:

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[5] The fee applies to a generic new animal drug application subject to the criteria set forth in FDCA Section 512(d)(4).