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Via Certified Mail

The Honorable Robert F. Kennedy, Jr.
Secretary
United States Department of Health & Human Services
200 Independence Ave., S.W.
Washington, D.C. 20201

The Honorable Kyle Diamantas
Acting Commissioner
United States Food & Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dr. Michael Davis
Acting Director
Center for Drug Evaluation and Research
10903 New Hampshire Avenue
Building 51, Room 1109
Silver Spring, MD 20993

Re: Notice of Intent to Sue for Violations of the Endangered Species Act with Respect to Approval and REMS for Mifepristone

Dear Secretary Kennedy, Commissioner Diamantas, and Director Davis:

This letter serves as formal notice by Students for Life America (SFLA) and its affiliates, including Baylor Bears for Life and UT Law Students for Life, as well as their members, of violations of Section 7 of the Endangered Species Act (ESA) by the U.S. Food & Drug Administration and its Center for Drug Evaluation and Research (CDER) in connection with the approval and Risk Evaluation and Mitigation Strategies (REMS) issued for mifepristone.

SFLA, a 501(c)(3) charity, exists to recruit, train, and mobilize youth to abolish abortion, to provide policy, legal, and community support for women and their children, and to steward the environment as God's creation to protect it and the animals He has created from pharmaceutical pollution—especially abortion pollution. SFLA and its affiliate members care about the environment, and its members nationwide have a vested interest in protecting the environment from

pollution, protecting endangered species and habitats from destruction, and preserving these species and habitats for future generations to see and experience. SFLA seeks to prevent the dumping of mifepristone into the waterways of the United States and the inevitable harm that has occurred and will continue to occur for endangered species.

As detailed below, research shows that mifepristone, as a consequence of its discharge into wastewater and its persistence in the environment, may affect species protected under the Endangered Species Act. Yet the FDA did not consult with the U.S. Fish and Wildlife Services and National Marine Fisheries Service (the "Services") concerning those effects. Its failure to do so violated the ESA.

The EPA has raised significant concern over harm to animals from pharmaceutical waste—that is, pharmaceutical byproducts that enter the environment following the use of medications by humans. "Medicines that we take are not entirely absorbed by our bodies; a portion is excreted into wastewater."[1] And according to the EPA, "[r]esearch shows that pharmaceuticals entering the environment through flushing or other means negatively affect aquatic ecosystems, including and fish and animal populations."[2] Indeed, fish and other aquatic wildlife are "much more vulnerable to certain types of emerging contaminants," including pharmaceuticals, which "have been shown to pose a risk … by affecting their ability to reproduce, altering their behaviour in ways jeopardising their survival, or through direct toxic effects."[3] "Aquatic pollution is particularly troublesome because aquatic organisms live in the contaminated water and are exposed continuously throughout their lifecycle."[4] Such risks follow from exposure to a variety of different drugs, particularly antibiotics, which "are designed to kill living organisms" and "are likewise poisonous to aquatic plants."[5]

Those substantial concerns about medications designed to kill bacteria are much greater for mifepristone, which is designed to kill humans. The FDA approved mifepristone in 2000 as the first drug used in the two-drug chemical abortion cocktail. Mifepristone is an oral medication that functions by blocking progesterone receptors in a developing embryo, thus effectively starving the fetus in utero.[6] On its own, mifepristone causes the demise of the unborn child as much as 80% of the time. And it is 99% effective when followed by misoprostol—the second drug in the chemical

[1] EPA, How Pharmaceuticals Enter the Environment, https://www.epa.gov/household-medication-disposal/how-pharmaceuticals-enter-environment#flushing (Jan. 22, 2026).
[2] EPA, The Impact of Pharmaceuticals Released to the Environment (Nov. 10, 2025), https://www.epa.gov/household-medication-disposal/impact-pharmaceuticals-released-environment.
[3] *Id.* (quotations omitted).
[4] *Id.*
[5] *Id.*
[6] 2023 Mifeprex Label at 10.

abortion regimen, which induces contractions to expel the fetus.[7] Plus, while the initial approval of mifepristone required dispensation exclusively in doctors' offices after an in-person appointment, in 2023, the FDA issued a new REMS that permits mifepristone to be prescribed without an in-person visit (and by mail, in violation of the Comstock Act).[8]

As a consequence of the FDA's actions, the concentration of mifepristone in wastewater, groundwater, and drinking water is on the rise. SFLA's analysis of data from the Guttmacher Institute suggests that each year, more than 50 tons of blood and placental tissue contaminated with mifepristone—along with human remains—are expelled into waterways. And numerous studies have detected mifepristone and related metabolites in water supplies both in Europe and in America.[9] Mifepristone's intended lethal effect, coupled with elevated concentrations in water, is a recipe for harm to all manner of life, including the species protected by the ESA.

These facts mandate inter-agency consultation over the effects of FDA's actions on protected species. The ESA requires that FDA consult with the Services to ensure that any agency "action authorized, funded, or carried out by such agency … is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of habitat of such species."[10] Actions subject to this standard include FDA approvals to market a product within its jurisdiction, including conditions set upon such approval.[11] And the ESA's implementing regulations mandate that "[e]ach Federal agency shall review its actions at the earliest possible time to determine whether any action may affect listed species or critical habitat."[12]

The regulations purposely set the "may effect" threshold as a low bar to ensure that "actions that have any chance of affecting listed species or critical habitat do so even if it is later determined that the actions are 'not likely' to require at least some

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[7] *Id.* at 13 tbl. 3.
[8] 18 U.S.C. § 1461.
[9] V.L. Marlatt, et al., *Impacts of endocrine disrupting chemicals on reproduction in wildlife and humans*, 208 Env't Research (2022); Sesethu Vumazonke, et al., *Detection of Pharmaceutical Residues in Surface Waters of the Eastern Cape Province*, Int. J. Environ. Res. Pub. Health (2020); Manvendra Patel, et al*., Pharmaceuticals of Emerging Concern in Aquatic Systems: Chemistry, Occurrence, Effects, and Removal Methods*, 116 Chemical Reviews (2019); Pavel Sauer, et al., *Two synthetic progestins and natural progesterone are responsible for most of the progestagenic activities in municipal wastewater treatment plant effluents in the Czech and Slovak republics*, 137 Water Research 64 (2018); M. Rucins, et al., *Determination of Hormone Antagonists in Waste-Water Samples by Micellar Electrokinetic Chromatography*, 81 Chromatographia 1607 (2018); Elise Rose, PhD & Michael Varveris, M.D., *Anti-Progesterone in Environmental Water*, 41 Issues in Law & Med. (2026).
[10] 16 U.S.C. § 1536(a)(2).
[11] *Inst. for Fisheries Res. v. United States Food & Drug Admin.*, 499 F. Supp. 3d 657, 667 (N.D. Cal. 2020).
[12] 50 C.F.R. § 402.14.

consultation under the Endangered Species Act."[13] The analysis includes an examination of both the direct effects of the action as well as its indirect effects, which are defined as "those effects that are caused by or will result from the proposed action and are later in time, but are still reasonably certain to occur."[14] And agencies are bound to consult except when their actions will have "no effect" on listed species.

FDA did not engage in any such consultation under the ESA for its actions regarding mifepristone—neither for the initial approval nor for any of its subsequent REMS. FDA's failure to assess mifepristone's direct, indirect, and cumulative adverse effects to endangered species and their habitats may have significant consequences to those species. For example, freshwater mussels, including the Balcones Spike,[15] and the Texas Fawnsfoot,[16] Fatmucket,[17] and Pimpleback,[18] are uniquely vulnerable to such exposures, given their particular susceptibility to chemical pollution from wastewater effluent. And pharmaceutical pollution is a special concern—for example, studies have shown that even at low environmental concentrations, antidepressant metabolites in wastewater imperil mussel health by causing embryotoxicity and affecting antioxidant/detoxification enzymes.[19] The effect of mifepristone, the purpose of which is to kill an embryo, could be expected to be much more severe—indeed, since studies have shown that mifepristone in water can cause reversal of sex in fish, its effect on smaller organisms is likely to be even more pronounced.[20]

Federal law requires consultation under the ESA to prevent these situations and to ensure no harm to such species. But the FDA blew past those guardrails here. And it is difficult to envision how its approval of mifepristone and its decision to make it readily available by mail would *not* affect endangered and threatened species.

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[13] *Karuk Tribe of Cal. v. U.S. Forest Se*rv., 681 F.3d 1006, 1028 (9th Cir. 2012*); see al*so U.S. Fish & Wildlife Serv. and Nat'l Marine Fisheries Serv., Endangered Species Consultation Handbook at xvi (Mar. 1998) (emphasis in original) (discussing the low "may affect" threshold, which is met whenever "a proposed action may pose any effects on listed species or designated critical habitat").

[14] 50 C.F.R. § 402.2.

[15] U.S. Fish & Wildlife Service, Balcones Spike, https://www.fws.gov/species/balcones-spike-fusconaia-iheringi.

[16] U.S. Fish & Wildlife Service, Texas Fawnsfoot, https://www.fws.gov/species/texas-fawnsfoot-truncilla-macrodon.

[17] U.S. Fish & Wildlife Service, Texas Fatmucket, https://www.fws.gov/species/texas-fatmucket-lampsilis-bracteata.

[18] U.S. Fish & Wildlife Service, Texas Pimpleback, https://www.fws.gov/species/texas-pimpleback-quadrula-petrina.

[19] *See* Ayesha Rafiq, *Antidepressants and their metabolites primarily affect lysosomal functions in the marine mussel, Mytilus galloprovincialis*, Sci. of the Total Enviro. (2023).

[20] *See* Jing Cai et al., *Effects of long term antiprogestine mifepristone (RU486) exposure on sexually dimorphic lncRNA expression and gonadal masculinization in Nile tilapia (Oreochromis niloticus)*, Aquatic Toxicology (2019); *see also* V.L. Marlatt, et al., *Impacts of endocrine disrupting chemicals on reproduction in wildlife and humans*, 208 Env't Research (2022); Kathryn E. Arnold, et al., *Medicating the environment: assessing risks of pharmaceuticals to wildlife and ecosystems*, Philos. Trans. R. Soc. B Biol. Sci. (2014).

Many species may be impacted by the FDA's failure to adhere to its statutory duty, including the following:

West Indian Manatee
Mexican wolf
Gulf Coast jaguarundi
Ocelot
Mexican long-nosed bat
Whooping crane
Eskimo curlew
Red-cockaded woodpecker
Northern Aplomado Falcon
Mexican spotted owl
Piping Plover
Golden-cheeked warbler
Southwestern willow flycatcher
Hawksbill sea turtle
Leatherback sea turtle
Kemp's ridley sea turtle
Texas blind salamander
Houston toad
San Marcos salamander
Barton Springs salamander
Big Bend gambusia
Clear Creek gambusia
Comanche Springs pupfish
Fountain darter
Pecos gambusia
Leon Springs pupfish
Devils River minnow
Arkansas River shiner
Ouachita rock pocketbook
American burying beetle
Coffin Cave mold beetle
Kretschmarr Cave mold beetle
Tooth Cave ground beetle
Comal Springs riffle beetle
Comal Springs dryopid beetle
Rhadine infernalis Beetle
Helotes mold beetle
Rhadine exilis Beetle
Bee Creek Cave harvestman
Bone Cave harvestman
Tooth Cave pseudoscorpion
Tooth Cave spider
Cokendolpher Cave Harvestman
Government Canyon Bat Cave spider
Madla Cave Meshweaver
Robber Baron Cave Meshweaver
Government Canyon Bat Cave meshweaver
Peck's cave amphipod
Star cactus
Pecos sunflower
Zapata bladderpod
Ashy dogweed
South Texas ambrosia
Tobusch fishhook cactus
Texas poppy-mallow
Nellie's cory cactus
Bunched cory cactus
Lee pincushion cactus
Sneed pincushion cactus
Kuenzler hedgehog cactus
Black lace cactus
Davis' green pitaya
Lloyd's Mariposa cactus
Gypsum wild-buckwheat
No common name
Slender rush-pea
Walker's manioc
Texas trailing phlox
Little Aguja Pondweed
Hinckley oak
Navasota ladies-tresses
Texas snowbells
Texas wild-rice
Large-fruited sand-verbena
Terlingua Creek cat's-eye
Chisos Mountain hedgehog Cactus
American chaffseed
White bladderpod
Texas prairie dawn-flower
Texas ayenia
Pecos assiminea snail
Texas golden Gladecress
Bracted twistflower
Texas Hornshell
Dunes sagebrush lizard

Sharpnose Shiner	Pecos amphipod	rufa red knot
Prostrate milkweed	Neches River rose-mallow	Loggerhead sea turtle
Louisiana pinesnake	Guadalupe fescue	Texas fawnsfoot
Peppered chub	Yellow-billed Cuckoo	Northern Long-Eared Bat
Diamond Tryonia	Salado Salamander	Whooping crane
Phantom Springsnail	Smalleye Shiner	Green sea turtle
Gonzales tryonia	Diminutive Amphipod	Eastern Black rail
false spike	Jollyville Plateau Salamander	Guadalupe Orb
Georgetown Salamander	Mexican blindcat (catfish)	Guadalupe Fatmucket
Phantom Tryonia	American alligator	Cactus ferruginous pygmy-owl
Austin blind Salamander		Balcones spike

SFLA previously filed a Citizens Petition to raise these issues with FDA. In denying that petition in the first days of 2025, FDA maintained that these actions are not subject to the ESA consultation requirement and that there is no evidence of environmental harm from mifepristone. Neither position is tenable.

First, the ESA plainly applies. FDA is plainly an "agency" and a drug approval and the conditions on it are both "actions" under the ESA. The ESA's implementing regulations define "action" broadly to include "the granting of licenses, contracts, leases, easements, rights-of-way, permits, or grants-in-aid."[21] Courts have thus held that other FDA approvals were unlawful where they did not undertake adequate consultation under the ESA.[22] The actions of FDA and CDER in granting pre-market approval for mifepristone and setting the conditions therefor are no different. Nor is the FDA's contention that the ESA's consultation mandate was limited to "discretionary" decisions of any help. Even accepting that premise, the FDA's decision here is discretionary at best. It was plainly not mandatory for FDA to approve a prescription pharmaceutical with an indication to kill and to make it available by mail in violation of federal criminal law.

Second, the facts set forth above show plainly that there is ample evidence of environmental harm from mifepristone, well enough to satisfy the low bar that it "may affect" a listed species. The FDA cannot avoid its consultation requirement by arguing with that evidence. Rather, it has a duty under ESA regulations to determine, "at the earliest possible time" either that "the proposed action is not likely to adversely affect any listed species" or that it "may affect" a listed species.[23] But the FDA did neither—instead, its actions with respect to mifepristone have ignored the ESA entirely. And even if substantial compliance were a defense, the FDA did not

[21] 50 C.F.R. § 402.02.
[22] *Institute for Fisheries*, 499 F. Supp. 3d at 667.
[23] 50 C.F.R. § 402.14(a)-(b); 16 U.S.C. § 1536(a)(2).

conduct anything that could be characterized as substantial compliance with the ESA—its environmental review for mifepristone focused on potential human harms, not on harms to other species. Rather, it was conducted at a time when FDA contemplated dispensation of mifepristone solely by physicians in doctor's offices, not under the FDA's new regime of mail-order abortion.

FDA is thus in violation of Section 7 of the ESA for failing to engage in consultation with the Services in connection with approving mifepristone and issuing REMS for it. SFLA, its affiliates, and its members enjoy recreating, observing, and studying endangered species impaand have plans to continue doing so in the future. By failing to follow the substantive and procedural requirements of the ESA, FDA has injured and continues to injure SFLA, its affiliates, and their members. Per this notice, the ESA gives FDA 60 days to resolve these violations. If it does not do so, we will pursue litigation. Should you wish to discuss this matter, please contact me.

Sincerely,

/s/ Lincoln Davis Wilson
Lincoln Davis Wilson

Counsel for Students for Life America, Inc., Baylor Bears for Life, and UT Law Students for Life

cc:

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