Citizen Petition: Over-the-Counter Classification of Ivermectin Tablets

June 26, 2025
Dockets Management Staff
Food and Drug Administration (FDA)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Citizen Petition

The undersigned Petitioner, Dr. Simone Gold, on behalf of America's Frontline Doctors (AFLDS), submits this petition under 21 C.F.R. § 10.30 and in accordance with 21 U.S.C. § 353(b)(3) and 21 C.F.R. § 310.200(b), to request that the FDA initiate rulemaking to switch ivermectin (IVM) oral tablet products from prescription-only status to full over-the-counter (OTC) status. This request encompasses the FDA-approved indications of ivermectin (intestinal strongyloidiasis and onchocerciasis), as well as the additional use of ivermectin for prophylaxis and early outpatient treatment of COVID-19 in adults under appropriate labeling.

Action Requested

Petitioner requests that the Commissioner of Food and Drugs exempt ivermectin oral tablet products from prescription-dispensing requirements pursuant to 21 U.S.C. § 353(b)(3) and 21 C.F.R. § 310.200(b). This exemption would permit ivermectin to be marketed and sold as an OTC medication for its current FDA-approved indications and for the prophylaxis and treatment of mild-to-moderate COVID-19 in adults, as directed by the proposed OTC labeling. Specifically, Petitioner requests that the FDA initiate the necessary rulemaking or regulatory action to reclassify ivermectin to nonprescription status, on the basis that prescription-only requirements are **"not necessary for the protection of the public health"** given ivermectin's safety profile, and that the drug **"is safe and effective for use in self-medication as directed in proposed labeling."**

In addition, Petitioner requests that the FDA review the proposed OTC Drug Facts labeling (attached herein) and the protocol outlines for label comprehension and self-selection studies included in this petition, and provide feedback or concurrence as needed to facilitate the transition of this product to OTC status. Petitioner is prepared to promptly undertake any necessary data collection, in collaboration with the FDA, to support this switch. Finally, Petitioner asks the FDA to acknowledge recent state-level regulatory developments (e.g. in Arkansas, Tennessee, and Idaho) that have broadened public access to ivermectin, and to work in

concert with public health authorities to ensure that federal regulations align with the emerging consensus that OTC availability of ivermectin can be accomplished safely and beneficially for public health.

Statement of Grounds

1. Background on Ivermectin (Approved Uses and Safety)

Approved Uses: Ivermectin is a broad-spectrum antiparasitic agent that has been used in humans for over three decades. Orally administered ivermectin tablets are FDA-approved to treat intestinal strongyloidiasis (threadworm infection) and onchocerciasis (river blindness).[1] These tropical parasitic diseases have been traditionally treated with single or short-course weight-based doses of ivermectin, with millions of treatments administered in global public health campaigns. Ivermectin is also used **off-label** for other parasitic and dermatologic conditions (e.g. scabies, lice, filariasis), and is available in topical formulations for indications like rosacea. The discoverers of ivermectin's avermectin class were awarded the Nobel Prize in 2015, reflecting the drug's enormous impact on human health.

Safety Profile: Ivermectin has an exceptionally well-established safety profile in humans. It has been used **extensively (hundreds of millions of doses)** in mass drug administration programs for onchocerciasis and other infections, often with only minimal medical supervision.[2] Numerous studies report low rates of adverse events when ivermectin is given at approved doses, with most side effects being mild and transient. Reported side effects from standard oral doses (e.g. 0.2 mg/kg) include mild itching, dizziness, headache, nausea, or transient hypotension in some patients. Serious adverse reactions are exceedingly rare. Notably, **no significant increase in adverse events** has been observed in randomized trials of ivermectin vs. placebo for COVID-19. A recent systematic review of 33 RCTs involving 10,489 patients found that ivermectin did **not** increase the risk of serious adverse events compared to controls (and in fact showed a slight reduction in overall adverse events, RR ~0.87).[3] This indicates that ivermectin's tolerability in a trial setting was at least on par with placebo or standard care. Ivermectin's margin of safety is high when used as directed; doses up to 10 times the approved antiparasitic dose have been used in trials for other diseases with only modest increases in mild side effects.[4]

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[1] "Ivermectin and COVID-19." *U.S. Food & Drug Administration*, 5 Apr. 2024, www.fda.gov/consumers/consumer-updates/ivermectin-and-covid-19.

[2] Crump, A. Ivermectin: enigmatic multifaceted 'wonder' drug continues to surprise and exceed expectations. *J Antibiot* 70, 495–505 (2017). https://doi.org/10.1038/ja.2017.11. Retrieved from Nature Portfolio.

[3] Song, Zhilong et al. "Ivermectin for treatment of COVID-19: A systematic review and meta-analysis." *Heliyon* vol. 10,6 e27647. 11 Mar. 2024, doi:10.1016/j.heliyon.2024.e27647. Retrieved from PubMed Central Database.

[4] Crump, A. Ivermectin: enigmatic multifaceted 'wonder' drug continues to surprise and exceed expectations. *J Antibiot* 70, 495–505 (2017). https://doi.org/10.1038/ja.2017.11. Retrieved from Nature Portfolio.

Important safety considerations are well-understood and can be conveyed through labeling. For example, **taking extremely large doses** of ivermectin can be dangerous and may lead to neurological effects (ataxia, seizures, coma),[5] so the OTC labeling will clearly instruct consumers not to exceed the recommended dosing. Ivermectin can also interact with certain medications (e.g. blood thinners), so a warning to consult a doctor or pharmacist before use if the individual is on specific high-risk concomitant drugs will be included. Ivermectin is not known to have significant organ toxicity; unlike many OTC pain relievers (acetaminophen, NSAIDs) that carry risks of liver, kidney, or gastrointestinal damage, ivermectin does not cause injury to major organs at therapeutic doses. The primary rare serious hazard of ivermectin—encephalopathy in patients with heavy **Loa loa** (African eye-worm) infection[6]—is only relevant in certain African populations and is not a concern for the typical U.S. consumer using ivermectin for labeled indications. Overall, ivermectin's **"extremely good safety profile"** has been documented in literature, and it is considered one of the safest medications in its class. This safety record underpins the case that ivermectin can be used without direct physician supervision when clear OTC instructions are provided.

2. Scientific Evidence of Ivermectin's Efficacy Against COVID-19 (Early Treatment and Prophylaxis)

Rationale: Since the start of the COVID-19 pandemic, ivermectin has been investigated as a repurposed agent for prophylaxis and treatment of SARS-CoV-2 infection. Its **in vitro** antiviral activity against SARS-CoV-2 was noted early in the pandemic, and multiple clinical studies have since been conducted with mixed results. The FDA has thus far not authorized ivermectin for COVID-19, stating that available trial data did not demonstrate efficacy to the agency's satisfaction.[7] However, a growing body of peer-reviewed literature, especially emerging after 2022, supports that **ivermectin may confer clinical benefits** in the context of early COVID-19 treatment or prevention. Petitioner submits that while definitive large-scale trials have yielded varied outcomes, the totality of evidence – including meta-analyses and real-world observational data – supports the inclusion of COVID-19 prophylaxis and mild treatment as appropriate OTC uses for ivermectin, provided consumers are properly informed by labeling. Key evidence is summarized below.

Prophylaxis (Pre-Exposure or Post-Exposure): Substantial data indicate that regular prophylactic use of ivermectin can significantly reduce the risk of contracting COVID-19. A landmark large-scale prospective program in Itajaí, Brazil followed **88,012 adult subjects**

[5] "Ivermectin and COVID-19." *U.S. Food and Drug Administration*, 5 Apr. 24, www.fda.gov/consumers/consumer-updates/ivermectin-and-covid-19.
[6] Campillo, Jérémy T et al. "Serious adverse reactions associated with ivermectin: A systematic pharmacovigilance study in sub-Saharan Africa and in the rest of the World." *PLoS neglected tropical diseases* vol. 15,4 e0009354. 20 Apr. 2021, doi:10.1371/journal.pntd.0009354. Retrieved from PubMed Central Database.
[7] "Ivermectin and COVID-19." *U.S. Food and Drug Administration*, 5 Apr. 24, www.fda.gov/consumers/consumer-updates/ivermectin-and-covid-19.

offered ivermectin prophylaxis during 2020. In that program, among participants who elected to take ivermectin prophylactically (at ~0.2 mg/kg on two consecutive days every 15 days), COVID-19 **infection, hospitalization, and mortality rates were dramatically lower** than in those who did not take ivermectin.[8] After rigorous propensity score matching to control for age and comorbidities, **regular ivermectin users had a 49% lower COVID-19 infection rate and a 92% lower COVID-19 mortality rate compared to non-users**. Even **irregular** users (who took some ivermectin but did not adhere to the full regimen) experienced an intermediate benefit (e.g. 32% lower infection rate vs. non-users). This dose-responsive relationship (no use < irregular use < regular use) strongly indicates a real prophylactic effect attributable to the drug. In fact, non-use of ivermectin was associated with a **12.5-fold higher mortality risk** from COVID-19 compared to regular use in this analysis. These striking results, published in a peer-reviewed journal (Cureus, 2022), suggest that a properly dosed ivermectin regimen can markedly reduce the risk of COVID-19 outcomes at the population level. While the Itajaí study was observational in nature (participants self-selected whether to use ivermectin prophylaxis), the **magnitude of effect and dose-response trend** make it unlikely that bias alone explains the findings. Smaller randomized trials of ivermectin prophylaxis have reported consonant results – for example, a 2021 systematic review noted that in three RCTs (736 total subjects), **ivermectin prophylaxis significantly increased the likelihood of preventing COVID-19 infection** compared to no prophylaxis (relative risk of infection significantly reduced).[9] Although those trials were limited and of variable quality, their outcomes align with the large-scale data. Given this evidence, Petitioner proposes that ivermectin be labeled for **"prevention of COVID-19 in adults at high risk of exposure"** (such as individuals with a household member who is positive, healthcare workers during outbreaks, or those in congregate settings during surges). An example prophylactic regimen, consistent with that used in the Brazilian program, would be weight-based dosing approximately **0.2 mg/kg once weekly** (note: 0.4 mg/kg every two weeks was the program's protocol). This falls within known safe dosage limits and offers a convenient weekly schedule for consumers.

Early Outpatient Treatment: The efficacy of ivermectin in treating COVID-19 (especially mild to moderate illness in outpatient settings) has been the subject of numerous trials and meta-analyses. Admittedly, some **high-profile randomized controlled trials** did not find a statistically significant benefit on their primary endpoints. For example, the NIH-funded **ACTIV-6** trial and the Brazilian **TOGETHER** trial (published in 2022 in the New England Journal of Medicine) concluded that ivermectin did not reduce the rate of COVID-19

[8] Kerr, Lucy et al. "Regular Use of Ivermectin as Prophylaxis for COVID-19 Led Up to a 92% Reduction in COVID-19 Mortality Rate in a Dose-Response Manner: Results of a Prospective Observational Study of a Strictly Controlled Population of 88,012 Subjects." *Cureus* vol. 14,8 e28624. 31 Aug. 2022, doi:10.7759/cureus.28624. Retrieved from PubMed Central Database.

[9] Cruciani, Mario et al. "Ivermectin for Prophylaxis and Treatment of COVID-19: A Systematic Review and Meta-Analysis." *Diagnostics (Basel, Switzerland)* vol. 11,9 1645. 8 Sep. 2021, doi:10.3390/diagnostics11091645. Retrieved from PubMed Central Database.

hospitalization compared to placebo in the studied populations.[10] However, these trials had important limitations: in many cases **treatment was initiated relatively late** (up to 7 days after symptom onset in the TOGETHER study) and the patient populations included low-risk individuals, potentially underpowering the studies to detect differences in severe outcomes. When examining the broader set of clinical evidence, a very favorable picture emerges. **Multiple meta-analyses** now synthesize data across dozens of trials, and most report favorable outcomes with ivermectin. Please see C19IVM.org with 281 studies (52 RCTs and 61% lower risk for early treatment).[11] A 2023 systematic review and meta-analysis encompassing **33 RCTs (10,489 patients)** found **statistically significant improvements in certain key outcomes** for ivermectin-treated patients.[12] Notably, patients receiving ivermectin had a significantly lower risk of progressing to mechanical ventilation (pooled RR ~0.67, 95% CI 0.47–0.96) compared to controls. This suggests that ivermectin might reduce the likelihood of severe respiratory failure in COVID-19. The same meta-analysis reported **no difference in all-cause mortality** between ivermectin and control groups, but the authors noted that many trials were not large enough individually to assess mortality, and some had high risk of bias. Another analysis (Bryant et al. 2021, Am J Ther) that included a mix of randomized and observational studies reported a significant survival benefit with ivermectin, though that finding has been debated.[13] In terms of virological efficacy, ivermectin has demonstrated the ability to **accelerate viral clearance**. An earlier meta-analysis (Szalenko et al. 2022) found that ivermectin significantly shortened the duration of viral shedding: on average, patients cleared the virus about **5.7 days faster** with ivermectin than with placebo in the analyzed trials.[14] Faster viral clearance correlates with quicker recovery and lower infectiousness. Clinically, some RCTs have also noted more rapid improvement in symptoms (e.g. fever, cough) in the ivermectin arms, although results vary by study.

In summary, while the highest levels of evidence (large RCTs) have not universally confirmed a benefit, there is **substantial evidence of efficacy** for ivermectin in early COVID-19. The **balance of data** suggests that when used **early in the course of a mild infection**, ivermectin may reduce the risk of progression (by limiting viral replication and inflammation) and potentially shorten illness duration. At worst, ivermectin appears to perform comparably to placebo in rigorous trials (with no harm done), and at best it can improve outcomes in a

[10] Reis, Gilmar et al. "Effect of Early Treatment with Ivermectin among Patients with Covid-19." *The New England Journal of Medicine*. vol. 386,18 1721-1731. 30 Mar. 2022, DOI: 10.1056/NEJMoa2115869. Copyright 2022 - Massachusetts Medical Society. Retrieved from The New England Journal of Medicine.
[11] "Ivermectin for COVID-19: Real-time Analysis of 281 Studies.", (n.d.), c19ivm.org/.
[12] Song, Zhilong et al. "Ivermectin for treatment of COVID-19: A systematic review and meta-analysis." *Heliyon* vol. 10,6 e27647. 11 Mar. 2024, doi:10.1016/j.heliyon.2024.e27647. Retrieved from PubMed Central Database.
[13] Andrew Hill, Manya Mirchandani, Victoria Pilkington, "Ivermectin for COVID-19: Addressing Potential Bias and Medical Fraud." *Open Forum Infectious Diseases*, Volume 9, Issue 2, February 2022, ofab645, https://doi.org/10.1093/ofid/ofab645. Retrieved from Oxford Academic Database.
[14] Ragó, Z., Tóth, B., Szalenko-Tőkés, Á. et al. "Results of a systematic review and meta-analysis of early studies on ivermectin in SARS-CoV-2 infection." *GeroScience* 45, 2179–2193 (2023). https://doi.org/10.1007/s11357-023-00756-y. Retrieved from Springer Nature Link.

meaningful subset of patients – especially in the context of variants or settings where other treatments may be inaccessible. Petitioner emphasizes that **early outpatient treatment for COVID-19 remains an area of unmet need**, as many patients are advised to simply isolate and monitor symptoms until they worsen. An OTC ivermectin option could empower such patients to initiate proactive treatment during that critical early window, possibly preventing hospitalization. Given ivermectin's favorable safety profile and some signals of efficacy (even if modest), the **benefit-risk calculation** for OTC availability is strongly positive in the context of a public health emergency. Importantly, any **uncertainty in efficacy can be managed through labeling** (e.g. instructing users that ivermectin is not a substitute for standard medical care if symptoms progress, and that they should seek medical attention if they worsen). Overall, the evidence supports making ivermectin available OTC with appropriate information, so that consumers – in consultation with pharmacists or through their own informed judgment – can decide to use it for COVID-19 prevention or treatment.

3. State-Level Policy Actions Supporting OTC Access to Ivermectin

In the absence of federal action to reclassify ivermectin, several U.S. states have moved independently to facilitate easier access to this medication for their populations. These legislative and policy developments underscore a growing recognition at the state level that ivermectin can be safely distributed without the usual prescription controls. They also reflect public demand for ivermectin as an accessible option for COVID-19 prevention and treatment. While state laws cannot alter federal drug approvals, they can remove state-level barriers (such as pharmacy dispensing restrictions) and thereby demonstrate real-world models of nonprescription ivermectin use. We urge the FDA to take note of these trends, as federal OTC status would create a uniform and well-regulated framework nationwide, replacing the current patchwork approach. Key state-level developments include:

- **Tennessee:** In 2022, Tennessee enacted a law allowing ivermectin to be dispensed by pharmacists without a prescription. The state legislature passed the bill (SB2188) by wide margins, and it became law with the Governor's signature.[15] This made Tennessee the first state to explicitly permit **OTC or pharmacist-facilitated sale of ivermectin** for human use. The law was intended to ensure residents could obtain the drug easily for COVID-19, reflecting policymakers' judgment that the benefits outweighed risks. News reports noted that ivermectin would "soon be available without a prescription in Tennessee" despite ongoing debates about efficacy. Since implementation, Tennesseans have been able to request ivermectin directly from pharmacies under the conditions of the

[15] Farmer, Blake. "Tennessee Will Make Ivermectin Available Without a Prescription, despite Research Showing No Benefit for COVID Treatment." *WPLN News*, 7 Apr. 2022, wpln.org/post/tennessee-to-make-ivermectin-available-without-a-prescription-despite-research-showing-no-benefit-for-covid-treatment/.

law, and there have been no reported public health crises stemming from this access.

- **Arkansas:** In March 2025, Arkansas approved **Act 725** (formerly SB 12), which authorizes over-the-counter sale of ivermectin in the state. The bill was signed by Governor Sarah Huckabee Sanders, making Arkansas one of the few states to fully deregulate human ivermectin at the state level.[16] The law enjoyed broad support in the Arkansas legislature, with legislators citing both the potential benefits against COVID-19 and a philosophical trust in individuals to make their own healthcare decisions. As a result of this law, Arkansans can purchase ivermectin tablets without a prescription as of mid-2025. This bold step again reflects the view that **OTC availability can be done safely**; indeed, the law's proponents argued that ivermectin is well-known and "magical" in its potential (albeit contentiously) and that people's common sense can be trusted.[17]

- **Idaho:** As of April, 2025, Idaho's Governor signed **Senate Bill 1211**, making ivermectin available without prescription in Idaho pharmacies.[18] The law was passed with emergency provisions to take effect immediately, highlighting the urgency felt by Idaho lawmakers. Idaho's deregulation of ivermectin occurred even as the FDA maintains its stance against use for COVID-19, illustrating a divergence between state and federal perspectives. Notably, Idaho's law does not even require a pharmacist consultation – it outright allows **OTC sale** on store shelves. During hearings, the Idaho Retailers Association did raise a practical point: without an FDA-approved OTC label, pharmacies had hesitated to stock ivermectin on shelves. This underscores the need for FDA action: state laws can permit sale, but an official OTC labeling from FDA would equip pharmacies with the necessary informational labeling to sell the product responsibly (one reason this petition seeks FDA-approved labeling). Idaho joined the small but growing list of states taking legislative action to bypass prescription status for ivermectin.

- **Others (Kansas, South Carolina, New Hampshire, etc.):** Several states have pursued similar initiatives through legislation or regulatory changes. **Kansas** introduced HB 2126 in 2023 to authorize OTC purchase of ivermectin (and hydroxychloroquine) tablets,[19] and

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[16] Lenora, Josie. "New Arkansas Law Allows Over-the-counter Ivermectin Sales." *Little Rock Public Radio*, 26 Mar. 2025, www.ualrpublicradio.org/local-regional-news/2025-03-26/new-arkansas-law-allows-over-the-counter-ivermectin-sales.

[17] Ibid.

[18] Pfannenstiel, Kyle. "In Idaho, Ivermectin Can Be Sold over the Counter — After Gov. Little Signs Bill." *Idaho Capital Sun*, 14 Apr. 2025, idahocapitalsun.com/briefs/in-idaho-ivermectin-can-be-sold-over-the-counter-after-gov-little-signs-bill/.

[19] "Bill Text: KS HB2126 - 2023-2024 - Regular Session - Introduced - Kansas House Bill 2126 (Prior Session Legislation)." *LegiScan*, (n.d.) legiscan.com/KS/text/HB2126/id/2658071.

a parallel Senate Bill 173 was also considered.[20] These efforts signal strong support within Kansas for easier ivermectin access. **South Carolina** lawmakers introduced bills (H.3916 and H.4042) to amend state law to allow OTC sale of ivermectin tablets without a prescription.[21] [22] These bills indicate bipartisan recognition that pharmacists or retailers should be empowered to provide ivermectin to adults over 18 upon request. **New Hampshire's** legislature actually approved a bill in 2022 (HB 1022) that would have allowed pharmacists to dispense ivermectin under a standing order to anyone who wanted it; although that bill was ultimately vetoed by the Governor,[23] the passage by the House and Senate demonstrated substantial legislative support for the concept. Other states such as **Arizona, Oklahoma, and Mississippi** have seen public campaigns or legislative proposals aimed at protecting doctors who prescribe ivermectin or making it more accessible, reflecting a broader movement during the pandemic to **remove barriers to ivermectin**.

In summary, there is an **emerging trend at the state level** to facilitate OTC or behind-the-counter access to ivermectin. States like Tennessee, Arkansas, and Idaho have already implemented such policies, effectively treating ivermectin as an OTC product within their borders. These actions, taken together, provide a valuable case study: none of these states have reported an upswing in adverse events or misuse since loosening access (to the contrary, they have likely reduced incidents of people resorting to animal products). The FDA should not ignore the fact that a segment of the medical and patient community – as evidenced by these laws – believes that the **public can use ivermectin safely on their own**. Instead of a patchwork of state laws with potentially variable quality controls, a uniform FDA-sanctioned OTC switch would ensure **consistent labeling, quality, and monitoring** nationwide. It would also affirm the FDA's responsiveness to both patient needs and real-world evidence, aligning federal policy with on-the-ground realities. We urge the FDA to view these state initiatives as supportive evidence that the **time is ripe for a national OTC switch** for ivermectin.

Lastly, it is true that Petitioners submitted a similar petition seeking the conversion of hydroxychloroquine to OTC status in mid-2020 (pg. 13). Hydroxychloroquine and ivermectin have been treated very similarly during the pandemic. Both are old, safe, repurposed drugs used for early, outpatient treatment of COVID. Petitioners submit that much has changed since their

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[20] "Kansas SB173." *PolicyEngage - Legislative Tracking*, (n.d.) trackbill.com/bill/kansas-senate-bill-173-authorizing-the-over-the-counter-purchase-of-ivermectin-tablets-and-hydroxychloroquine-tablets/2358386/.

[21] "South Carolina General Assembly 126th Session, 2025-2026 - H. 3916." *South Carolina Legislature*, 6 Feb. 2025, www.scstatehouse.gov/sess126_2025-2026/bills/3916.htm.

[22] "SC H4042 - 2025-2026 - 126th General Assembly - South Carolina House Bill 4042 (In Recess)." *LegiScan*, (n.d.) legiscan.com/SC/bill/H4042/2025.

[23] "New Hampshire Gov. Chris Sununu Vetoes Bill to Dispense Ivermectin by Standing Order." *CBS News*, 26 Jun. 2022, www.cbsnews.com/boston/news/covid-19-ivermectin-new-hampshire-chris-sununu/.

previous petition in 2020. Petitioners respectfully suggest that the hostility shown by the FDA toward ivermectin during the pandemic severely harmed the agency's credibility. The FDA publicly mocked ivermectin as "horse medicine"[24] in its "most successful social media post in its history." After litigation was brought by frontline doctors, the FDA was forced to reverse its antipathy toward ivermectin. Apter v. Department of Health and Human Services, 80 F.4th 587 (5th Cir. 2023). The Fifth Circuit Court of Appeals took the FDA head on, beginning its decision, "You are not a horse" and later the "FDA is not a physician." Id. at 1-2.

During that litigation,[25] the FDA publicly claimed that it was not impeding physician prescribing of ivermectin - despite its very public social media campaign against it. As all of this happened at a time of great public interest in the subject, the public correctly became very suspicious of the FDA. "The Apter court held that FDA did not have general authority to make pronouncements regarding public health, and that statements made without specific statutory authority were ultra vires, and unlawful. FDA can disseminate information, but not medical recommendations."[26]

Should the FDA now take steps to make this safe drug available to American consumers, it would help the FDA begin to repair the extensive reputational harm it inflicted upon itself.

4. Proposed OTC Labeling

To support the safe and effective use of ivermectin in an OTC setting, Petitioner has prepared a draft **Drug Facts** for labeling. These materials are intended to satisfy the requirements for an OTC switch by ensuring that consumers have the information needed to use the product properly.

Draft OTC Drug Facts Label (Ivermectin 3 mg Tablets):

Below is a proposed labeling format for an OTC ivermectin tablet product. This draft focuses on key information for both the antiparasitic indications and the COVID-19 related uses. Final labeling would be refined in consultation with the FDA to ensure clarity and compliance with all OTC labeling regulations.

Drug Facts (proposed) – **Ivermectin Tablets, 3 mg** (oral)

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[24] Hiltzik, Michael. "Column: FDA Shoots Itself in the Foot by Settling a Groundless Lawsuit over Its Ivermectin Warnings." *Los Angeles Times*, 26 Mar. 2024. Retrieved from Yahoo Finance.

[25] "20220602_Ivermectin Complaint (Final)." *Court Listener*, 2 Jun. 2022, storage.courtlistener.com/recap/gov.uscourts.txsd.1875135/gov.uscourts.txsd.1875135.1.0_1.pdf.

[26] Berman, Jonathan, and Colleen M. Heisey. "Apter v Department of Health and Human Services." *Food & Drug Law Institute*, 22 May 2024. Retrieved from FDLI website. https://www.fdli.org/2024/05/apter-v-department-of-health-and-human-services/#:~:text=An%20appeal%20ensued.%20The%20Fifth%20Circuit%20reversed,to%20state%20a%20claim%20under%20the%20APA

- **Active Ingredient:** Ivermectin 3 mg (in each tablet)

- **Purpose:** Antiparasitic

Uses:

- Treats intestinal **strongyloidiasis** (threadworm infection) in adults that has been diagnosed by a doctor.

- Treats **onchocerciasis** (river blindness) in adults diagnosed by a doctor.

- Prophylaxis for COVID-19 in adults who are at high risk of exposure (for example, living with someone who has COVID-19, or during community outbreaks) – **use for this purpose is one tablet per 30 kg of body weight (≈0.2 mg/kg) once weekly** as needed, not to exceed 4 tablets (12 mg) per dose.

- Treats early mild-to-moderate **COVID-19** in adults (confirmed or suspected COVID-19 with mild symptoms) – **use for this purpose is one tablet per 15 kg of body weight (≈0.4 mg/kg) per day for 2 days**. Start as soon as possible after symptoms begin or a positive test. (For example, an adult weighing 60–90 kg would take 4 to 6 tablets once daily for 2 days.)
  (COVID-19 use is not FDA-approved; however, FDA is allowing OTC use under this labeling).

Warnings:

- **Do Not Use** if you have ever had an allergic reaction to ivermectin.

- **Ask a doctor before use if you have**: liver disease; kidney disease; are taking anticoagulant (blood thinner) medications or other prescription drugs; or have a condition causing a weakened immune system.

- **When using this product**: Follow the dosing directions carefully. Taking more than directed may cause serious effects (such as nausea, dizziness, low blood pressure, nervous system effects). Do not take for COVID-19 if you have severe symptoms such as difficulty breathing, chest pain, confusion, or if you have fainted – seek immediate medical care in those cases.

- **Stop use and ask a doctor if**: Your condition worsens or fails to improve. For COVID-19, if fever or other symptoms persist more than 5 days or worsen (e.g. trouble

breathing), stop taking this product and get medical help. For parasitic infections, if symptoms of infection persist or recur after treatment, consult a doctor (you may need follow-up testing).

- **If pregnant or breastfeeding,** ask a health professional before use. (Pregnancy warning: use in pregnancy only if clearly needed – discuss with your doctor.)

- **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions:

- **For intestinal strongyloidiasis (adult):** Take **200 µg per kg** as a single dose. This equals **1 tablet per 15 kg body weight** taken one time. (Examples: 4 tablets one time for a 60 kg person; 6 tablets one time for a 90 kg person.) Take on an empty stomach with water.

- **For onchocerciasis (adult):** Take **150 µg per kg** as a single dose. This equals **1 tablet per 20 kg body weight** taken one time. (Examples: 3 tablets one time for a 60 kg person; 5 tablets one time for a 100 kg person.) A repeat dose may be needed in 3–12 months per doctor's recommendation.

- **For prevention of COVID-19 (adult):** Take **1 tablet (3 mg) per ~30 kg** body weight **once weekly** during ongoing exposure risk. (Examples: 2 tablets weekly for up to 60 kg person; 3 tablets weekly for 61–90 kg; 4 tablets weekly for >90 kg. Do not exceed 4 tablets per dose.) Swallow tablets with or after a meal. If exposure continues, you may take weekly for up to 4 weeks, then re-evaluate need with a healthcare professional.

- **For early treatment of COVID-19 (adult):** Take **1 tablet (3 mg) per ~15 kg** body weight **once daily for 2 days**. (Examples: 4 tablets daily x 2 days for ~60 kg; 6 tablets daily x 2 days for ~90 kg.) Take on a full stomach with water. Start treatment as soon as possible after a positive test or onset of mild symptoms. If symptoms are still present after 2 days of dosing, you may continue **once-daily dosing for up to 5 total days** in consultation with a doctor. Do not exceed 5 days of treatment without medical advice.

- **Children:** This product is **not** for use in individuals under 18 years of age for COVID-19 uses. For antiparasitic uses in children weighing over 15 kg (33 lbs), consult a doctor for proper dosage.

Other Information:

- Store at room temperature (15–30°C / 59–86°F) and protect from light.

- Each tablet contains: lactose (inactive ingredient) – consult your doctor before use if you have an intolerance to certain sugars.

- Lot No. & Expiration Date: see package.

(Note: This OTC labeling includes COVID-19 related directions based on available protocols and safety data. Consumers should read all warnings.)

Proposed Packaging: The product would be packaged in bottles with a **clear dosing chart** to help consumers determine the number of tablets to take based on their weight for each indication. (We do not recommend blister packs as the typical dose is four or more tablets at one time.) A QR code or link to an official website could be provided for consumers to access more information (e.g. FAQs, detailed illustrations of dosing, and guidance on when to seek medical attention).

Environmental Impact

Petitioner claims a categorical exclusion from the requirement to prepare an environmental assessment or environmental impact statement, pursuant to 21 C.F.R. §§ 25.30 & 25.31. The requested action does not increase the use of any active moiety to the point of significant environmental introduction. Ivermectin is already in widespread use; switching it to OTC is not expected to significantly alter the overall amount entering the environment. The drug will continue to be produced and used in similar total quantities (any increase in usage for COVID-19 prophylaxis would likely be offset by decreased use of veterinary formulations or illicit channels). The manufacturing and waste disposal associated with ivermectin will remain essentially the same. No extraordinary circumstances indicating a potential environmental effect are known. If the FDA believes an environmental assessment is required, Petitioner will promptly provide the necessary information.

Economic Impact

In accordance with 21 C.F.R. § 10.30(b), economic impact information will be provided upon request by the Commissioner. Here we note, in brief, that granting this petition could have several economic benefits. **Consumers** may save on healthcare costs by obtaining ivermectin OTC (eliminating the need for a physician visit solely to get a prescription, and enabling purchase of low-cost generic ivermectin tablets). The price of generic ivermectin is expected to remain affordable due to competition among manufacturers, and OTC status could further lower

costs through over-the-counter market efficiencies. **Healthcare systems** could benefit if wider prophylactic or early treatment use of ivermectin helps reduce COVID-19 hospitalizations, thereby avoiding costly inpatient care. Even a modest reduction in severe cases could translate to significant economic savings given the high expense of hospitalization. There may also be indirect cost savings by **preventing misuse of veterinary ivermectin**; when human OTC products are available, incidents of improper use of animal products (and resultant poison control calls or ER visits) should diminish, avoiding those healthcare expenditures. Manufacturers and retailers may incur some costs to update labeling and conduct required studies, but these are normal business investments associated with bringing an OTC product to market. Because ivermectin is off-patent and produced by many firms, no single company bears an undue burden, and market competition should keep consumer prices low. Overall, the economic impact on FDA or regulated industry is expected to be minimal (since no new molecular entity is introduced, only a status change), while the impact on consumers and public health is positive in terms of cost savings and improved access.

Precedent, Legal History, Politicization of the Citizen's Petition

There are innumerable examples of medications converting from prescription to over the counter status. For example: ibuprofen (Advil, Motrin), naproxen (Aleve), loratadine (Claritin), cetirizine (Zyrtec), fexofenadine (Allegra), omeprazole (Prilosec), lansoprazole (Prevacid), esomeprazole (Nexium), famotidine (Pepcid), Nicoderm, Afrin, Dramamine and many others. Citizen Petitions have played a role in prompting the FDA to consider or re-evaluate prescription-to-OTC switches in several cases. The most well-known example is Plan-B, but also Opill and Narcan in 2023.

Following Judge Edward Korman's 2013 ruling in Tummino v. Hamburg, a landmark decision addressing FDA delay and political interference in the over-the-counter approval process, citizens expect their petitions to be carefully considered without political interference. In Tummino the Court noted that the citizen's process had been heavily (and improperly) politicized. The Court observed that "the decisions of the Secretary [of the HHS] and the FDA were arbitrary, capricious, and unreasonable" as well as "The motivation for the Secretary's action was obviously political" as well as "The agency's denial of full OTC access was not based on scientific evidence, but on unacceptable political considerations" as well as "If the FDA had acted on the 2001 Citizen Petition in a timely and lawful manner, Plan B would have been available without a prescription for all ages for a decade."

We the undersigned submitted a similar petition in mid-2020 for hydroxychloroquine and we believe our original petition was as politicized as the Court found in Tummino. The Secretary of HHS has publicly discussed the dreadful results of our COVID policies. "During COVID, we had in this country 16% of the global COVID deaths - we only have 4.25% of the global population. Something we were doing was utterly wrong." Various epidemiologists including Dr.

Jay Bhattacharya, now the Director of the NIH, and Dr. Harvey Risch, have estimated that 50-75% of the deaths could have been averted with widespread access to early treatment medications. Each testified to this before the Senate in November and December 2020.

We respectfully request a dispassionate analysis of the scientific facts pertaining to ivermectin.

Certification

The undersigned certifies that, to the best of our knowledge and belief, this petition includes all information and views upon which the petition relies, and it includes representative data and information known to the Petitioner which are unfavorable to the petition. All scientific data referenced herein have been presented in good faith, whether they support or weigh against the requested action, in order to provide a balanced and truthful record. Petitioner understands the importance of complete transparency in FDA's decision-making for OTC switches and has not withheld any relevant information.

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Date: June 26, 2025

References: Some sources are cited in-text in the format of hyperlinks.