August 21, 2025

VIA ELECTRONIC SUBMISSION

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

SCORPION CAPITAL LLC CITIZEN PETITION RE: VYKAT XR

Dear Sir or Madam:

The undersigned, on behalf of Scorpion Capital LLC ("Scorpion" or "Petitioner"), submits this Citizen Petition ("Petition") pursuant to 21 C.F.R. §10.20 and §10.30 and related relevant provisions of the Federal Food, Drug and Cosmetic Act (the "FDCA") or the Public Health Service Act or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs ("Commissioner") to request the Commissioner to issue a regulation, request recalls, revise industry guidance, and take such other actions set forth below.

The FDA approved VYKAT XR on March 26, 2025, for the treatment of hyperphagia in adults and pediatric patients 4 years of age and older with Prader-Willi syndrome. We understand the drug became commercially available in mid-April. Petitioner has recently conducted a four-month-long investigation into VYKAT XR's purported safety and efficacy. The findings were published on August 15, 2025 as a 415-page investigative report, enclosed as part of this petition as Appendix A and highlighted infra.

Petitioner is aware of three reports in recent weeks of young patients hospitalized for potential heart failure shortly after starting VYKAT XR. In the last few days, new information has emerged which suggests the total number of hospitalizations may be seven patients or higher.

The timeline and sequence that Petitioner infers from these reports suggests that these patients were in the earliest cohort of new drug starts shortly after approval, indicating an alarming safety signal on a very small base of patients. The unfolding situation exhibits signs consistent with a potentially unprecedented post-approval safety scenario and merits immediate review by the FDA. The emerging trend leads Petitioner to fear a potential flood of similar cases in the coming weeks and months as more patients begin the drug. The possibility that one or more of these cases could turn fatal cannot be ruled out, as one of these reports concerns an 11-year old who spent 7 weeks in the hospital, including a week on a ventilator. Thus, Petitioner asks the FDA to request Soleno Therapeutics to undertake a voluntary recall of VYKAT XR from market.

Petitioner is concerned that Soleno's management team is evincing a complacent and perhaps even dismissive posture toward the gravity of the situation, and appears ill-equipped to address this crisis. On the company's recent Aug 6, 2025 quarterly earnings call, the CEO made statements to the public that downplay any new safety signal: "I can tell you that we have not seen anything in the post-marketing setting that is different from the clinical trial setting. So there are no new safety signals."

In the midst of multiple reports of children hospitalized for potential heart failure, Soleno's CEO instead appears to have spent recent days catering to Wall Street hedge funds over luncheons and dinners, providing them with new details regarding the number of total hospitalizations while neglecting – as far as we are currently aware - to issue a press release or safety alert to the public, so that physicians and patients are in possession of the same critical, new safety information as holders of his stock.

The CEO's talking points during these private investor forums, as documented in research notes distributed to Wall Street clients of Soleno's underwriters, downplay these adverse events as being "on label" – a callous and flippant dismissal, one that gives the impression the company sees the label as a license to hospitalize children without consequence. In one of these forums on Tuesday evening (Aug 19th), the CEO declined to specifically detail the nature of the recent hospitalizations, indicating only that they were for pulmonary/respiratory events and "events related to hyperglycemia."

Hyperglycemia does not land a patient in the hospital, making us wonder if his artful phrasing was perhaps code for diabetic ketoacidosis, and whether he views a catastrophic safety event like DKA as just another elevation of blood glucose levels. During this same forum, we are of the understanding that the CEO passed the buck to prescribers, allegedly stating that "the package insert specifically talks about all of these things…the idea is that physicians need to take care of that."

Petitioner notes that Soleno is a small company with only 131 employees listed on LinkedIn. VYKAT XR is the company's first drug launch, and it is unclear whether the management team has any prior launch experience. We question if Soleno has simply punted safety-related responsibilities to its specialty pharmacy, and whether it has the requisite capability and level of seriousness to navigate a safety crisis. An Aug 18th research note by one of its underwriters (Guggenheim) stated that Soleno's "pharmacovigilance team" has been "largely unsuccessful" in tracking patients which Petitioner's report indicated may be at risk of a severe adverse event. We question whether such a dedicated team even exists, much less its size or experience.

Petitioner is dumbfounded that Soleno lacks the capability to track down these patients given the very small number of total patients on drug; more so given that contact information for each patient, we presume, is instantly accessible via its specialty pharmacy (Panther). This suggests that Soleno is already far out its depth and woefully unprepared to market a drug with such a severe adverse event profile, and thus Petitioner asks the FDA to intervene and employ the full force of its powers to prevent any further children from ending up in the ICU.

Petitioner's concerns have intensified in the last few days as new information has emerged which suggests a far larger number of hospitalizations than the three documented in our report. The company now appears to be disclosing a total of seven hospitalizations, as documented in a research note by Guggenheim Securities (Aug 18, 2025: "Flash Note"/"SLNO: Notes from Mgmt/Investor Meetings") and in investor meetings in recent days. The company asserted no new safety signal two weeks ago on its Aug 6th earnings call, but has now suddenly changed its tune in the aftermath of Petitioner's investigative report.

The note states that "so far, the company has received reports of 7 patients experiencing SAE"s that led to hospitalizations, out of hundreds of start forms (646 by June 30); all of these patients have since recovered." Given the other reports of hospitalizations for potential heart failure in recent weeks (detailed infra), a reasonable person may infer that some or all of these 7 hospitalizations may also involve similar pulmonary/cardiac-related complications. The lack of any further detail about the nature of these hospitalizations is troubling, such as the patients' age, time-to-onset, dosage, duration of hospitalization, and post-hospitalization complications.

It is unclear whether these 7 hospitalizations include the 3 reports of which Petitioner is aware. Moreover, a general rule of thumb is that only 10% of adverse events are reported. Thus, one cannot rule out the possibility of other cases of potential heart failure in recent weeks that are currently unknown to Soleno or Petitioner. Irrespective, whether the exact number is 7 or 10 or higher, the surge of hospitalizations this rapidly after FDA approval indicates a post-marketing safety crisis of the highest order.

Moreover, the use of a vague and unhelpful metric ("hundreds of start forms") as the denominator versus the actual number of patients on drug is consistent with what Petitioner infers to be an ongoing pattern of obfuscation regarding the magnitude of VYKAT XR's safety signal.

One piece of new information provided by Soleno suggests that the denominator may be ~135 patients. The Guggenheim note states that "as of August 15, 2025, SLNO reported 5.2% AE-related discontinuations for commercial VYKAT XR patients." If we reasonably assume that the 7 hospitalizations resulted in an AE-related discontinuation, that would imply a denominator likely no larger than 135 patients on drug (7 divided by 5.3%). Seven to ten reported hospitalizations out of 135 patients this rapidly after FDA approval would suggest that VYKAT XR has no viable path to remaining on market - particularly if all or some of these cases involved potential heart failure.

Details regarding 3 reports of potential heart failure in recent weeks:

Report #1: On Jul 20, 2025, a parent posted in an online forum – "We have been in the hospital since Friday!!! Retained fluid all over especially his lungs with potential heart failure. Stopping Vykat aka diazoxide choline for good!!!" Please refer to pages 4 and 12 of our report for the source citation and additional information regarding this case. The parent indicated the patient is 25; "had edema that was all around his lungs that led to hard of breathing"; was hospitalized for 4 days including diuretic therapy and oxygen tank; and was "instructed by endo to stop vykat asap." In a subsequent post the parent elaborated that "it was gradual over the past 2 mos he was on it"; "started with weezing [sic] hard to breathe etc."; "then just boom."

Report #2: On July 28, 2025, a second parent replied to the post above – "I am so sorry you went through this. We did as well. Our son is 11 and spent 7 weeks in the hospital this summer due to respiratory failure from fluid overload. He ended up on a vent for a week. Only change/new thing was the vykat and at the beginning of admission he'd been on it for 6 weeks, so almost max dose. He too is severely overweight and so the side effects weren't noticeable until it was too late. He was tested for everything possible, all negative. Final diagnosis was fluid overload from the vykat and its [sic] been reported to Soleno and the fda." Please refer to p.5 of our report for the source citation.

Report #3: On August 8, 2025, a third parent replied to the post above – "this was our experience too! Massive fluid overload cause fluid around my sons [sic] heart and lungs. Weve [sic] been working a month now to get the fluid off with Lasix and pt." The parent elaborated in a second post that her son was in the hospital for 5 days and that "now we make weekly cardiology visits, a ton of labs, and are followed by pulmonology." Please refer to p.6 and 13 of our report for the source citation.

In addition, Petitioner is observing numerous online reports of parents indicating symptoms consistent with potential creeping fluid retention, potential pulmonary edema, and diabetic ketoacidosis. The parents do not appear to realize the gravity of the symptoms they are sharing publicly and how quickly they can tip in to full crisis. Reports of fluid overload are surging and parents are resorting to warning other parents online (Report, p.26/27). Parents are reporting cases of kids no longer able to walk or put on their socks or shoes due to swelling; periorbital edema around the eyes, and so forth.

Remedial measures such as diuretics, monitoring, slower titration, or label changes are unlikely to mitigate the emerging safety crisis.

The labeled warnings and precautions section states "Risk of Fluid Overload: Edema, including severe reactions associated with fluid overload, has been reported. Monitor for signs or symptoms of edema or fluid overload."

The warning is woefully inadequate and is obviously failing to prevent hospitalizations. The literature is unequivocal that diazoxide mechanistically causes fluid retention. Thus, the Pediatric Endocrine Society (PES) practice guidelines (2020) "strongly recommend that a thiazide diuretic be started concomitantly with the initiation of diazoxide due to risk of fluid retention and PH" – "twice a day"; "higher doses may be required." (Report, p. 21).

In the absence of diuretics, the guidelines make it clear that diazoxide leads to uncontrolled fluid retention and PH; thus the addition of diuretics is standard of care. However, the Soleno clinical trials studied VYKAT XR as a monotherapy, invalidating the safety data to date in the context of combination therapy with diuretics, if Soleno begins to now advise physicians to initiate diuretics concomitantly. Thus, Petitioner sees no option except recalling VYKAT XR from market – without diuretics patients are at risk of fluid retention and PH, but there is no safety data or study to justify placing PWS patients on this combo.

More importantly, diuretics in the context of chronic diazoxide therapy for PWS would not prevent serious adverse events. Thus, Petitioner believes that tragedy will continue to ensue as long as VYKAT XR is allowed to remain on market. The evidence strongly indicates that neither monitoring for signs of edema nor initiating diuretics will prevent cases of pulmonary edema and congestive heart failure.

1 Diazoxide's inherent toxicity is well-documented in the medical literature (Report, p.19/20/22). A 2021 paper (Desai et al, "The danger of diazoxide in the neonatal intensive care unit") indicates the existing literature vastly underestimates the danger of diazoxide-induced pulmonary hypertension and respiratory failure. In their review of safety outcomes over a 5-year period at a regional hospital, they stated that 33% of patients developed PH and 40% experienced respiratory failure vs. the current literature which indicates 2-7%. (source: https://journals.sagepub.com/doi/pdf/10.1177/20420986211011338)

2. A critical finding of the paper is that diazoxide-induced fluid retention CANNOT be mitigated with diuretics and that discontinuation of diazoxide was the only treatment option: "…three of eight patients received diuretics throughout the period of time that they developed respiratory deterioration and fluid overload"; "however, they did not show any signs of improvement until the diazoxide was discontinued."

3. The finding that diuretics are insufficient to prevent diazoxide-induced fluid overload and respiratory failure is consistent with extensive evidence piling up through case reports that parents are posting in the primary online forum for VYKAT XR discussion, as discussed in our report.

a. Report #3, detailed supra, indicates that we have "been working a month now to get the fluid off with Lasix and pt." This report suggests that fluid retention can be systemically persistent even a month after VYKAT XR discontinuation and diuretic therapy over that time.

b. A detailed case report describes attempts to pause VYKAT XR to initiate diuretics to mitigate edema, only to have the edema promptly return upon re-starting the drug, resulting in discontinuation. (Report, p.28/29)

4. Critically, diazoxide-induced edema is not dose dependent. We again quote Desai et al, 2021: "In addition, similar to the findings from the existing literature, the development of edema was not dose-dependent." In addition, Timlin et al, 2017 ("Development of Pulmonary Hypertension During Treatment with Diazoxide: A Case Series and Literature Review"): "review of the published cases, as well as those reported here, reveals little consistency in the time-to-effect"; "the pulmonary hypertension persisted when the dose was decreased from 12 mg/kg/day to 8 mg/kg/day, and only resolved once the diazoxide was discontinued entirely"; "it is not clear if the PH would have completely resolved at the lower dose with more time." (Source: https://pubmed.ncbi.nlm.nih.gov/28642988/).

We highlight this crucial point as Soleno appears to be downplaying and deflecting the adverse events as due to titration-related issues (per Aug 18 Guggenheim note, discussed supra: “Mgmt speculated that some SAEs may have occurred in patients that have not been titrated adequately onto the drug”; “Per mgmt, SLNO is encouraging slower titration and a lower max dose in order to minimize titration-related AE exacerbation.”).

5. Monitoring is ineffective, unrealistic, and will fail to prevent edema before it is too late. Fluid retention is extremely difficult to detect in PWS patients who frequently present with severe obesity. Thus, fluid retention creeps up and tips into crisis before caregivers are able to detect it. Petitioner provides images (Report, p25) which indicate that edema is indistinguishable from obesity in PWS patients, including a lower-body image of one of the children whom Petitioner believes to be the patient referenced in Report #2, detailed supra (“He too is severely overweight and so the side effects weren’t noticeable until it was too late.”)

6. Fluid retention tips into pulmonary crisis rapidly, as indicated in these case reports (Report #1: “started with weezing [sic] hard to breathe etc.”; “then just boom”). This leaves no window for timely diuretic therapy.

7. Parents are reporting concern that their PWS children are frequently non-verbal and unable to communicate distress associated with fluid retention and respiratory difficulties (Report, p.31). This makes any monitoring guidelines unrealistic in the PWS patient population.

8. Diuretics are far from benign. A leading authority in the PWS field and VYKAT XT trial investigator indicates significant concern that diuretics may exacerbate cardiac events and cause neurological ones like seizures (Report, p. 23). In addition, long-term, chronic loop diuretic therapy in PWS presents other dangers like acute kidney injury, arrythmia/QT prolongation, and hyperglycemia (Report, p. 24).

9. VYKAT XR in conjunction with growth hormone - used by most PWS patients as standard of care - synergistically increases the risk of edema. The P3 open-label extension paper indicates 82.4% of study participant were on growth hormone (Report, p.148). The fluid retention associated with GH is well-known in the literature. For example, Ho et al (Journal of Endocrinology, 2023): “the commonest adverse effect of GH replacement is fluid retention, which arises because of the anti-natriuretic action of GH.” In addition, Moller et al (Hormone Research in Pediatrics, 2004: “Growth Hormone and Fluid Retention”): “a major side effect of growth hormone (GH) administration is fluid retention.” (Sources: https://pubmed.ncbi.nlm.nih.gov/36524723/; https://pubmed.ncbi.nlm.nih.gov/10592455/)

Petitioner has significant concerns regarding the manner in which Soleno’s publications appear to repeatedly obscure and downplay the severe risk of fluid retention. The data also exhibits troubling irregularities, leading Petitioner to question the validity of the published safety information as well as the integrity of Soleno’s submissions to the FDA.

1. Pulmonary edema, a serious adverse event, is buried within Soleno’s adverse event tables (Report, p.139), with no transparent reporting or discussion in the publications for its phase 3 and open-label studies. PWS patients are uniquely vulnerable due to obesity, obstructive sleep apnea (OSA), hypotonia, low cardiac reserve, and GH deficiency. Chronic fluid overload may lead to eccentric hypertrophy ,HFpEF (heart failure with preserved ejection fraction), and hypertension.

2. Unusually, the edema adverse event data in the Prescribing Information and Medication Guide as part of the VYKAT XR FDA label do not match - and differ significantly from - that in the peer-reviewed Phase 3 publication – they are both the same data from the same study. In previous cases of scientific misconduct, we have found an inability to keep the same data set consistent to be a major red flag. The medication guide indicates edema in 27% of VYKAT XR patients (n=84) vs. 12% in placebo (n=42), while

the paper states 20.2% and 9.5%, respectively. Moreover, the guide states 27%/12% in a second section as well, indicating it is not a typo. (Report, p.140)

3. The prevalence of edema appears to increase the longer that VYKAT XR is used, with no apparent plateau – indicating that a tipping point is eventually reached whether discontinuation or a safety event. The open-label P3 extension study (C602) indicates edema in 30.4% of patients – exceeding the 20% in the Phase 3 paper. The average patient age in C602 was only 13.4 years. However, there is no way to extract the adverse events from the 1-year extension study because they are conflated with the previously reported P3 double-blind placebo-controlled study – which suggests to us an attempt to conceal longer-term rates of edema during in the extension period. (Report, p.141).

4. Soleno obscures the alarming level of fluid retention by conflating it in its studies as an increase in lean body mass (LBM), by using DEXA scans to assess LBM. As explained in our report, we think the purported body composition improvements are illusions caused by edema. DEXA artifact is well-known in this context, and Soleno's omission of this obvious issue is, we believe, part of the cover-up. A May 2025 paper by lead investigator Jennifer Miller and Soleno's Neal Cowen leads us to infer a shocking 16 lb steady and linear increase in fluid over 3 years of VYKAT XR – brazenly asserted to be LBM but which we think is clearly fluid. (Report, p.145-147)

5. We are troubled that Soleno assessed electrocardiogram (ECG) results during the P3 study but the paper buries the results with no mention of ECG - which would capture abnormalities consistent with drug-induced heart strain, pulmonary hypertension, hypoxia-related changes, fluid overload, electrolyte-related changes, and hERG/QT elongation. The heavily-redacted Study Protocol and Statistical Analysis plan states that ECG's were conducted at visit 1 for baseline, visit 6, and visit 7 at completion – "a trained cardiologist at the study site will review the ECG output and provide an assessment of the intervals, segments, abnormalities of T-wave or U-wave morphology"; "descriptive statistics for heart rate, RR interval, PR interval, QRS interval, QT interval, and QT interval corrected with Fridericia's (QTcF) formula and the change from baseline to each postbaseline visit will be presented." (Report, p.149).

Risk/reward imbalance warrants immediate market withdrawal. VYKAT XR lacks evidence of efficacy; and even if it was efficacious, the labeled indication for hyperphagia/appetite reduction cannot justify hospitalization and heart failure risks.

VYKAT XR is not a cure for PWS. It merely addresses one of numerous symptoms (hyperphagia) associated with a complex genetic condition. In addition, Soleno appears to be marketing extreme, unrepresentative cases of hyperphagia as the norm. For example, our report quotes endocrinologists who have attended recent marketing meetings with VYKAT XR drug reps: "whether it was manipulative or not…all people, to a degree, are trying to sell something…"; "I did feel like they were overemphasizing the horror stories…in my experience, my current patients don't have that…"; "they told a lot of horror stories… the amount of mailings and things I've got… I don't remember the last time I got this much…"

Moreover, the evidence submitted to the FDA in support of VYKAT XR's efficacy is lacking in credibility; and, at any rate, is clearly contradicted by real-world, post-approval reports posted by parents in the largest online forum for VYKAT XR-related discussion, which indicate that the drug is either ineffective or backfiring by increasing hyperphagia, which we believe to be consistent with the drug's actual vs. purported mechanism of action, as discussed in our report.

1. The pivotal phase 3 study did not show a statistically significant reduction in hyperphagia. We understand that the FDA was poised to reject approval as of that point, but relented after a petition campaign by two Prader-Willi patient associations. The petition lacked credibility, claiming "more than 26,000 comments from PWS families and their supporters" – exceeding the number of PWS patients in the US (Report, p.37). We also wonder if these associations had received monies from Soleno.

2. We highlight that the phase 3 study had an extremely low bar, and thus its failure is even more telling. It was merely a 13-week study with a highly-subjective caregiver questionnaire (HQ-CT) as the primary endpoint. Moreover, numerous trial investigators we interviewed as part of our investigation, in addition to former employees of Soleno, stated that the trials were functionally unblinded by adverse effects (hypertrichosis/hairiness, edema, different smell between drug vs. placebo), thus introducing placebo bias – a critical issue in the context of a survey instrument vs. a hard, biomarker-based endpoint. That the trial failed despite all of these methodological flaws in Soleno's favor is a resounding indictment of VYKAT XR's claims of efficacy.

3. The FDA yielded after the petition campaign and allowed Soleno to proceed with a highly unusual 16-week randomized withdrawal study. A quick glance at the purported results is sufficient to infer that it makes a mockery of the scientific method. Among other red flags:

a. We are unable to locate a published manuscript for the study in a peer-reviewed journal. Thus, we are left to wonder if the paper would not hold up to the scrutiny of a peer review process; or if the company wishes to bury the data from the public. The lack of a published paper at this point post-FDA approval strikes us as extremely unusual.

b. The withdrawal study was only 16 weeks in duration with only 77 trial participants. We have been told by multiple ex-employees of Soleno that the study's enrollment was heavily, unusually skewed to one site (University of Florida, Gainesville). Moreover, the ex-employees questioned the manner in which the study was conducted at this particular site, which leads us to doubt the validity of the study's results. (Report, p.40-44).

c. The results of this study strain credibility, at face value. One does not need to be a statistician to note the obvious red flags. The 16-week study exhibits a rather sharp and fortuitous separation in HQ-CT scores in the placebo arm (n=39) vs. drug (n=38) only in the last 4 weeks of the trial (+4.5 pbo, +0.4 drug). A winning sprint at the finish line is obviously suspicious, raising concerns of data integrity. Thus, we see a squeaker of a p-value of 0.049 in week 12, the second to last interval - a touch below the 0.05 threshold for statistical significance, once again suspicious. We are of the understanding, based upon ex-employee interviews, that even Soleno was surprised at the "extreme" spike in HQ-CT scores at the very end in the placebo arm – the flimsy foundation of the drug's efficacy and the FDA's approval. (Report, p. 39/41)

4. Real-world reports indicate that VYKAXT XR is actually increasing hyperphagia (Report, p. 45-47, 157-181). Some parents are reporting the worst hunger and food-seeking behavior they have seen in their kids, since beginning the drug. We think this is entirely predictable based upon the drug's actual vs. purported mechanism of action (Report, p. 45-47). One of the most commented upon posts in recent weeks (from July 16th) – in the primary online forum for VYKAT XR-related discission – concerns the drug leading to a "huge increase" in hyperphagia. (Report, p.7, 159-161).

A. Action Requested

This petition requests that the FDA take the following actions:

1. Request a voluntary recall of VYKAT XR from the US market, on the grounds that the drug presents a serious risk of adverse events, including hospitalization and potential heart failure, which outweigh its labeled indication.

2. Issue a formal public health advisory notifying prescribers, patients, and caregivers of the risks associated with VYKAT XR pending completion of the recall.

3. Take any additional regulatory or enforcement actions that FDA deems appropriate to ensure that patients are not exposed to unreasonable and avoidable risks from continued marketing of this drug.

We highlight two such additional actions which the FDA may deem appropriate, as possibilities for the agency's consideration. First, VYKAT XR could be transitioned to a compassionate use program in conjunction with a REMS protocol for current patients who may perceive a benefit, given the large placebo effect visible in the trials and as discussed in our report.

Second, Petitioner believes it may be helpful for the FDA to convene an Ad Comm to discuss the issues raised in the attached report as well as the actions requested in this Citizen Petition. Our report contains interviews with a significant proportion of the VYKAT XR trial investigators, many of whom expressed surprise at the FDA's approval and noted the drug's lack of efficacy and troubling safety profile. Given that many of those with a negative view of the drug are some of the most published and leading authorities in the PWS field, their input may assist the FDA in navigating an appropriate remedy.

B. Statement Of Grounds

In addition to all of the information detailed supra, and incorporated by reference, Petitioner has enclosed with this Citizen Petition (and incorporates herein) a 415-page investigative report and provides it as its statement of grounds (Exhibit A). The report presents detailed information concerning VYKAT XR's safety issues, in support of the actions requested in Section A.

Background on Petitioner and Petitioner's Report

Scorpion Capital LLC is an investment firm that specializes in investigative due diligence, primarily on biotechnology, pharmaceutical, medical device, and other life sciences companies. Petitioner expends considerable time and resources on each investigation, which typically lasts a minimum of three months and involves interviews with 20-50 experts whom Petitioner identifies and engages. Petitioner believes its investigations have historically been viewed as credible, informative, and helpful by the Department of Justice and the Securities and Exchange Commission.

Petitioner previously submitted a Citizen Petition on Apr 4, 2023, (docket number FDA-2023-P-1273) regarding Harmony Biosciences drug pitolisant, marketed as Wakix. The FDA issued a 13-page final response on June 21, 2024. While Petitioner respectfully disagrees with the FDA's final determination, Petitioner is grateful for the agency's thorough and careful consideration of the issues raised in the Petition, as reflected in its comprehensive response.

Petitioner submitted a Citizen Petition on January 14, 2025 (docket number FDA-2025-P-0182), regarding TransMedics Organ Care System. The FDA issued an interim response on June 3, 2025, and thus the Petition remains active. Petitioner is grateful for the agency's careful review of the issues presented.

C. Environmental Impact

Petitioner claims a categorical exclusion under 21 C.F.R. § 25.30 and § 25.31, as the relief requested in this Citizen Petition will have no environmental impact and therefore an environmental assessment or environmental impact statement is not required.

D. Economic Impact

Pursuant to 21 C.F.R. § 10.30(b), economic impact information will be submitted by the Petitioner only upon request of the Commissioner following review of this Petition.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all the information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,

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Appendix A

Petitioner's investigative report dated August 15, 2025. PDF link for public download:

https://scorpionreports.s3.us-east-2.amazonaws.com/SLNO1.pdf