U.S. FOOD & DRUG ADMINISTRATION
Office of Inspections and Investigations

October 18, 2024

Javier Alan Rios
JR Imports LLC
4001 S. Shary Road, Suite 550-3
Mission, TX 78572-1614

Re: Docket No. FDA-2024-P-2625

Dear Mr. Rios,

The U.S. Food & Drug Administration (FDA) received your Petition for Stay of Action and Request for Confidential Treatment (FDA-2024-P-2625) ("the Petition") on May 21, 2024.[1] The Petition states that it is submitted under Title 21 of the Code of Federal Regulations 21 CFR § 10.35[2] and identifies "the intended implementation of Import Alert #99-41 by the U.S. Food and Drug Administration (FDA) regarding the detention without physical examination of human and animal foods imported by JR Imports" as the subject of the Petition.

The Petition refers to FDA's May 13, 2024 letter titled "Detention Without Physical Examination Letter" with a reference of CMS # 661014. This letter notified you that the FDA was "taking steps to add foods that you import to Import Alert #99-41, 'Detention Without Physical Examination of Human and Animal Foods Imported from Foreign Suppliers by Importers Who Are Not in Compliance with the Requirements of the Foreign Supplier Verification Program (FSVP) Regulation.'"

Your Petition requests, in relevant part, that:

1. Pursuant to 21 CFR § 10.33(b), the Commissioner of Food and Drugs (Commissioner) reconsider the potential implementation of Import Alert #99-41, and instead allow JR Imports the opportunity to submit additional information and clarifications regarding its FSVP compliance.

2. Pursuant to 21 CFR § 10.35(b), the Commissioner stay the implementation of Import Alert #99-41 pending reconsideration of the matter by the Commissioner.

3. The Commissioner stay the effective date of any public disclosure or implementation of Import Alert #99-41 concerning JR Imports' imported foods. This request is made pursuant to 21 CFR § 10.35. (Pet. at 1-2).

[1] The petition is dated in error as May 17, 2025.
[2] We treat this petition as being submitted under 21 CFR § 10.33 and 10.35 due to the actions requested in the petition and other language indicating the filing under both sections ("e.g., … we request a stay of the Import Alert pending reconsideration of this petition.").

We have carefully reviewed your petition and other information available to the Agency. For the reasons outlined below, we are denying your requests.

I. Background

FDA concluded its initial FSVP inspection for your firm, JR Imports, on December 1, 2020. At this inspection, your firm confirmed that it did not have FSVP plans in place for any of its imported food products identified in its "list of imported foods and foreign suppliers," dated October 1, 2019 to September 30, 2020. FDA issued a Form FDA 483a—FSVP Observations—and, on May 10, 2021, again requested that your firm develop and provide FSVP records to FDA, but FDA did not receive a response.

FDA conducted a second inspection of your firm from August 5 through August 31, 2022. At this inspection, your firm again confirmed that it did not have FSVP plans in place for any of the food products identified in the "List of Imported Foods and Foreign Suppliers," dated August 1, 2021 to August 5, 2022. This list identified 63 different products from (b) (4) unique foreign suppliers. Your firm stated that it would comply with the FSVP regulation by researching other professionals to assist with developing FSVPs. FDA issued another Form FDA 483a and provided you fifteen working days to respond; FDA did not receive a response to the Form FDA 483a.

FDA issued your firm a warning letter on November 9, 2022, which explained several violations, including failure to develop, maintain, and follow an FSVP for any of the foods your firm imports. We received from your firm seven response letters, including supporting documentation, to this Warning Letter between December 2022 and March 2023. The responses included FSVP plans for three products from two foreign suppliers and identified sampling and testing as a verification activity in lieu of annual on-site audits. FDA requested your firm's written determination that sampling and testing provided adequate assurances that the foreign suppliers were producing the food in a manner that the hazards have been significantly minimized, as well as the associated records confirming the firm had completed the sampling and testing activities identified in their plans. Your firm's representative, Mr. Luciano Escobedo, stated that the records regarding sampling and testing that had been conducted would be provided to FDA by March 31, 2023. These records were not provided.

FDA conducted a follow-up inspection of your firm from April 20 through May 3, 2023. Firm management stated that they had developed an FSVP for seven imported food products from (b) (4) foreign suppliers but identified the remaining 53 products from (b) (4) suppliers as lacking an FSVP. We found that you did not make adequate corrections to the violations cited in the November 9, 2022 Warning Letter and issued another Form FDA 483a. The Form FDA 483a cited the following four observations: 1) failure to establish adequate written procedures for ensuring that appropriate foreign supplier verification activities are conducted with respect to a food you import; 2) failure to determine and document which verification activity or activities were needed to provide adequate assurances that a food you obtain from a foreign supplier is produced in compliance with processes and procedures that provide the required level of public health production; 3) failure to conduct and document or obtain documentation of one or more

supplier verification activities before importing the food into the United States; and 4) failure to develop an FSVP.

We received from your firm eleven responses to this Form FDA 483a between May 2023 and May 2024. One response pointed to the FSVP plans updated on March 30, 2023, which stated that the firm relies on its customers to ensure the food is processed to control the identified hazards and that it is not required to conduct an evaluation of a food and foreign supplier under 21 CFR § 1.505 or supplier verification activities under 21 CFR § 1.506.[3] *See* 21 CFR § 1.507(a)(4). However, your customer list included retailers (such as grocery stores whose customers are consumers that do not process such foods to control hazards as intended by the FSVP and other FDA regulations) and your firm did not describe any of the circumstances in 21 CFR § 1.507(a) that apply to your customers.

In your responses to the 2023 Form FDA 483a, you indicated that the produce you import was "rarely consumed raw" and therefore not subject to the same requirements under the Produce Safety Rule. Foods you import, including cilantro, prickle pear, radish, Welsh onion, and husk tomatillo, are "covered produce" as defined in 21 CFR § 112.3 and are not listed in 21 CFR § 112.2, which is an exhaustive list of foods considered to be "rarely consumed raw." FDA concluded that you failed to support your determination that these foods are not subject to FSVP requirements that ensure imported products are produced in a manner that provides the same public health protection as U.S. requirements. Additionally, your responses indicated that the process of developing FSVPs for the products identified during the inspection had begun but was not complete.

Further, your responses to the Form FDA 483a listed several identified hazards (Biological: pathogenic *Escherichia coli*, *Salmonella* spp., and *Listeria monocytogenes*; Chemical: pesticides[4]) requiring preventive controls for the prickle pear, cilantro, zucchini squash, prickle pear paddle, and Welsh onion. Your evaluation should have also determined whether hepatitis A virus in Welsh onion and *Shigella* and *Cyclospora cayetanensis* in cilantro are hazards requiring a control based on the available information about these hazards associated with these imported foods.

The responses you provided also included FSVPs describing your supplier evaluation and additional verification procedures. However, the foreign supplier evaluation records did not indicate whether you considered the foreign supplier's performance, including compliance with applicable food safety regulations (e.g., FDA's produce safety rule), in accordance with 21 CFR § 1.505(a)(1)(iii)(B). As another example, the FSVPs you provided did not meet the requirement to conduct and document (or obtain documentation of) one or more of the supplier verification

[3] The FSVP plan states JR Imports will receive at least annually, "Customer written assurance of implementing appropriate process controls." During the April and May 2023 inspection, management also stated that the firm was operating under 21 CFR § 1.507(a)(4) whereby the importer is not required to evaluate a food and its foreign supplier or carry out supplier verification activities because the circumstances in § 1.507(a) apply.

[4] Regarding your claim that 21 CFR § 1.507(a)(4) allowed your firm to not conduct evaluation or verification activities, it is not appropriate to rely on customers to provide assurance for pesticides. FDA has determined that pesticides are a hazard that requires a preventive control for produce from Mexico. Moreover, washing or peeling of the outer skin of produce is unlikely to remove pesticides that are absorbed through the roots and transported to the whole plant.

activities listed in 21 CFR § l.506(e)(l)(i) through (iv) for each foreign supplier before importing the food and periodically thereafter, as required by 21 CFR § 1.506(e). Specifically, you did not conduct and document any supplier verification activities for any of your foreign suppliers. You also stated you did not have FSVPs for the remaining foods you import.

In sum, you failed to comply with FSVP requirements for multiple years despite repeated FDA notifications[5] advising you of significant violations and providing you opportunities to demonstrate compliance. Compliance with FSVP requirements is an important part of protecting public health and ensuring imported food products are safe, wholesome, unadulterated, and properly labeled.

Based on this evidence, on May 13, 2024, FDA sent a letter to your firm advising you that FDA is taking steps to add foods that you import to Import Alert #99-41, "Detention Without Physical Examination of Human and Animal Foods Imported from Foreign Suppliers by Importers Who Are Not in Compliance with the Requirements of the Foreign Supplier Verification Program (FSVP) Regulation." The letter describes the reasons for that action and the steps that can be taken to address FDA's findings and request removal from the import alert. On May 22, 2024, FDA added your firm and specific products to Import Alert #99-41.[6]

II. Petition for Reconsideration

We turn now to your request that FDA reconsider implementation of the addition of JR Imports to Import Alert #99-41.

FDA's regulation at 21 CFR § 10.33(b) sets out the submission requirements of a petition for reconsideration as follows, in relevant part:

[5] As you have acknowledged, we have no obligation to hold a Regulatory Meeting and it is within FDA's discretion to move instead towards adding a firm to an import alert, especially where the firm has repeatedly failed to come into compliance.

[6] Import Alert #99-41 (at 109-113 in .pdf file of import alert, see https://www.accessdata.fda.gov/cms_ia/importalert_1160.html) lists the following products for JR Imports: Whole Grains/Milled Grain Products/Starches, Bakery Products/Dough/Mixes/Icings, Macaroni/Noodle Products, Cereal Preparations/Breakfast Foods, Snack Food Items, Milk/Butter/Dried Milk Products, Cheese/Cheese Products, Ice Cream and related Products, Filled Milk/Imitation Milk Products, Eggs/Egg Products, Meats, Meat Products and Poultry, Vegetable Protein Products, Fruit/Fruit Products, Nuts/Edible Seeds, Vegetables/Vegetable Products, Vegetable Oils, Dressing/Condiments, Spices, Flavors And Salts, Drinks, Soft Drinks, and Waters, Beverage Bases/Concentrates/Nectars, Coffee/Tea, Candy W/O Chocolate/Candy Specialties/Chewing Gums, Chocolate/Cocoa Products/Cocoa beans, Gelatin/Rennet/Pudding Mixes/Pie Fillings, Food Sweeteners/Nutritive syrups/honey/molasses, Multiple food dinners/Gravies/Sauces/Specialties, Soups, Prepared Salad Products, Baked Goods (Baby), Cereal (Baby), Veg (Baby), Fruit/Juice/Drink (Baby), Meat Prod/Comb Meat Dinner (Baby), Poultry Prod/Comb Poultry Dinner (Baby), High Meat Dinner/Cheese Food (Baby), Fish-Seafood Prod (Baby), Egg Prod (Baby), Pudding/Custard (Baby), Soups/Soup Mix (Baby), Pasta and Noodle Combination Dinners Without Meat, Market Basket Sampling, Baby Food N.E.C., Dietary Conv Food/Meal Replacements, Whole Edible Insects (adult and immature shapes), Milled Edible Insect Products, Edible Insect Bars, Edible Insect Bakery Products, Edible Insect Candy With Chocolate, Edible Insect Candy Without Chocolate, Edible Insect Capsules, Edible Insect Granola or Trail Mix, Edible Insect Jerky, Edible Insect Ice Cream and Related Products, Edible Insect Oils, Edible Insect Smoothies, Edible Insect Soups, Edible Insect Spreads And Pastes, Edible Insect Beverages, Edible Insect Protein: Simulated Meats and Tofu, Edible Insect Salts and Spices, Edible Insect Products N.E.C.

> An interested person may request reconsideration of part or all of a decision of the Commissioner on a petition submitted under § 10.25.

The regulation at 21 CFR § 10.33(d) sets forth the following standard for review of a petition for reconsideration of action as follows, in relevant part:

> The Commissioner may grant the petition when the Commissioner determines it is in the public interest and in the interest of justice. The Commissioner shall grant a petition for reconsideration in any proceeding if the Commissioner determines all of the following apply:
>
> (1) The petition demonstrates that relevant information or views contained in the administrative record were not previously or not adequately considered.
>
> (2) The petitioner's position is not frivolous and is being pursued in good faith.
>
> (3) The petitioner has demonstrated sound public policy grounds supporting reconsideration.
>
> (4) Reconsideration is not outweighed by public health or other public interests.

FDA is required to grant a petition for reconsideration of action only if all four of the elements in 21 CFR § 10.33(d) (as set out above) are met. As explained below, we find that the Petition did not meet the first and fourth of the four criteria in section 10.33(d). Consequently, we need not address the remaining two criteria.

With respect to the first criterion, the Petition failed to provide any information to demonstrate relevant information contained in the administrative record was not previously or not adequately considered per 21 CFR § 10.33(d)(1). In your petition, the only assertions as to information not previously or not adequately considered are that "[t]he agency . . . has not adequately considered JR Imports' FSVP submissions . . ." and that the FDA failed to "consider relevant evidence." Pet. at 4. These amount to general allegations devoid of factual specificity. They do not point out which submissions or which pieces of evidence were not considered. The allegations do not meet the standard described above in 21 CFR § 10.33(d)(1) or in 21 CFR § 10.33(b), which says that a petition must have a "full statement, in a well-organized format, of the factual and legal grounds upon which the petitioner relies" and "demonstrate that relevant information and views contained in the administrative record were not previously or not adequately considered" by the FDA.

Indeed, FDA's May 13, 2024, "Detention Without Physical Examination Letter" to JR Imports acknowledged receipt of multiple submissions from your firm in response to FDA warning letters and Forms FDA 483a and described how FDA considered the responses and determined whether they addressed any violations or observations identified in the warning letters or the Forms FDA 483a. For example, your responses dated December 5, 2022, December 8, 2022, December 15, 2022, December 21, 2022, January 4, 2023, January 31, 2023, and March 6, 2023, established sampling and testing as verification activities for your imported food products for all

identified hazards, as well as your written determination that the sampling and testing of agricultural products identified in our procedures provide adequate assurances that the foreign supplier is producing the food in a manner that the hazards requiring control have been significantly minimized or prevented, in lieu of initial and annual onsite auditing under 21 CFR § 1.505. However, as the letter noted, the responses did not provide records that the sampling and testing verification activities, as required by 21 CFR § 1.506(e)(1)(ii), were conducted.

As another example, the letter describes how FDA considered your responses dated May 23, 2023, July 7, 2023, August 10, 2023, September 7, 2023, October 2, 2023, November 1, 2023, November 25, 2023, December 27, 2023, February 27, 2024, April 5, 2024, and May 4, 2024, and found that: 1) they did not identify hazards requiring preventive controls; 2) they did not establish circumstances that would excuse you from conducting evaluations of a food and foreign supplier or supplier verification activities under 21 CFR § 1.507; 3) your firm was relying on inappropriate measures to control identified hazards; 4) your firm was incorrectly treating certain produce as rarely consumed raw; and 5) your records did not indicate that your firm considered the supplier's performance, including compliance with applicable food safety regulations, (e.g., FDA's produce safety rule) in accordance with 21 CFR § 1.505(a)(1)(iii)(B), among other findings. Accordingly, the Petition did not provide sufficient information to meet the first criterion and demonstrate FDA failed to previously or adequately consider relevant information contained in the administrative record.

For the fourth criterion in 21 CFR § 10.33(d), reconsideration must not be outweighed by public health or other public interests. We determine that reconsideration is outweighed by public health and other public interests. There remain ongoing failures to comply with important FSVP requirements. Specifically, JR Imports failed to demonstrate compliance with the FSVP requirements for over 60 products from at least 37 foreign suppliers during the time spanning October 2019 to present.

It is in the interest of public health and the public that imported food products are produced in a manner that provides the same public health protection as U.S. requirements and are safe, wholesome, unadulterated, and not misbranded. Congress directed FDA to promulgate the FSVP regulations in section 301 of the Food Safety Modernization Act (FSMA, Pub. L. 111-353), codified in section 805 of the FD&C Act (21 U.S.C. § 384a), to better protect public health and require importers perform risk-based foreign supplier verification activities to ensure that the food they import meets FDA's laws and regulations. This regulatory structure and oversight achieve public health objectives by ensuring accountability while maintaining flexibility for U.S. importers (see 80 FR 74226). Noncompliance with FSVP can result in FDA taking additional actions, such as refusing admission or adding noncompliant importers or products to import alerts (see 21 CFR § 1.514(a)). Accordingly, you have not provided any information showing that reconsideration would outweigh FDA's mission to protect public health and the public's interest in consuming safe food products.

The Petition must meet all four elements of 21 CFR § 10.33(d) for FDA to be required to grant it. Since two elements have not been met, FDA is not required to grant the Petition for Reconsideration.

III. Petition for an Administrative Stay of Action

FDA's regulation at 21 CFR § 10.35(a) provides:

> The Commissioner may at any time stay or extend the effective date of an action pending or following a decision on any matter.

FDA's regulation at 21 CFR § 10.35(b) sets out the submission requirements of a petition for stay of action as follows, in relevant part:

> An interested person may request the Commissioner to stay the effective date of any administrative action.

The regulation at 21 CFR § 10.35(e) sets forth the following standard for review of a petition for stay of action as follows, in relevant part:

> The Commissioner may grant or deny a petition, in whole or in part; and may grant such other relief or take such other action as is warranted by the petition. If, at any time, the Commissioner determines that changes in law, facts, or circumstances since the date on which the petition was submitted have rendered the petition moot, the Commissioner may dismiss the petition. The Commissioner may grant a stay in any proceeding if it is in the public interest and in the interest of justice. The Commissioner shall grant a stay in any proceeding if all of the following apply:
>
> (1) The petitioner will otherwise suffer irreparable injury.
>
> (2) The petitioner's case is not frivolous and is being pursued in good faith.
>
> (3) The petitioner has demonstrated sound public policy grounds supporting the stay.
>
> (4) The delay resulting from the stay is not outweighted [sic] by public health or other public interests.

Your Petition requests that FDA stay implementation of the addition of JR Imports to Import Alert #99-41 regarding the Detention Without Physical Examination of Human and Animal Foods Imported from Foreign Suppliers by Importers Who Are Not in Compliance with the Requirements of the Foreign Supplier Verification Program (FSVP) Regulation. JR Imports was added to Import Alert #99-41 on May 22, 2024. Accordingly, your request for stay is moot and subject to dismissal under 21 CFR § 10.35(e).[7]

Even if your petition were not moot, as stated in the regulation, the Commissioner shall grant a stay only if all four of the criteria in 21 CFR § 10.35(e) apply. As explained below, we find that

[7] Dismissal on the grounds of mootness under 21 CFR § 10.35(e) does not leave you without a potential remedy. Your request for reconsideration under 21 CFR § 10.33 is not moot and has been thoroughly addressed above.

the Petition failed to demonstrate the first of the four criteria in section 10.35(e). Further, the Petition did not address or provide any information at all about the second, third, and fourth criteria.

The Petition claims that the addition of JR Imports to Import Alert #99-41 causes irreparable harm to JR Imports. The Petition continues that adding JR Imports to the import alert would signal conclusive agency action that "could severely damage JR Imports 's [sic] reputation, disrupt its business relationships, and cause significant economic losses." Pet. at 3.

The Petition misunderstands the nature of FDA detentions and import alerts. Import alerts are not final agency action[8]; rather, they inform industry and FDA staff that the FDA has enough information to detain a product without physical examination.[9] Moreover, import alerts do not create a bar to importing any product.[10]

Imported food is subject to the provisions of the FD&C Act, including its requirements that each importer of food perform risk-based foreign supplier verification activities for the purpose of verifying that the food imported by the importer is produced in compliance with Section 419 of the FD&C Act (21 U.S.C. § 350h). FDA may refuse admission into the United States of an article of food offered for import pursuant to Section 801(a)(3) of the FD&C Act (21 U.S.C. § 381(a)(3)) if it appears that the importer is not in compliance with the FSVP requirements with respect to that food. 21 CFR § 1.514(a).

Before making any determination whether to refuse admission of a food, FDA detains the food, and the importer is entitled to notice of the reasons for the detention and an opportunity to be heard. *See* 21 CFR § 1.94(a). The importer may introduce either oral or written testimony to demonstrate the admissibility of the food. *See* 21 CFR § 1.94(a). That evidence is considered by an FDA field office, which decides whether to release the food, refuse admission, or allow the food to be brought into statutory compliance. *See* 801(a), (b) (21 U.S.C. § 381(a), (b)). An importer may seek reconsideration within the agency of an adverse decision and may seek judicial review. *See* 21 CFR §§ 10.33(a), 10.45, 10.75. Detention without physical examination is thus no bar to importing.

Similarly, placing a firm's product on an import alert does not lead to an inability to import product. The import alert serves to inform FDA field staff that the products appear to be in violation of FDA's laws and regulations and thus may be detained without physical examination.[11] A field office is not required to detain an article simply because it is listed on an import alert. For example, Import Alert #99-41, on which JR Imports is listed, states that field

[8] We also respond to this petition without determining whether the placement of a firm or product on an import alert is an administrative action as defined at 21 CFR § 10.3.

[9] Once an article is detained, FDA's ultimate determination whether to admit or refuse the article depends on the evidence submitted to it and the applicable statutory and regulatory requirements, not the import alert. See 21 CFR § 1.94(a).

[10] Contrary to your assertion, FDA's addition of JR Imports to Import Alert #99-41 does not constitute a "legislative rule." As explained herein and on Import Alert #99-41, import alerts do not create or confer any rights for or on any person, and do not operate to bind FDA or the public. FDA is not required to detain an article simply because it is listed on an import alert. Instead, import alerts say FDA "may detain" listed products.

[11] *See* FDA, *Import Alerts*, https://go.usa.gov/xAtu8.

staff "may detain without physical examination, an article of human or animal food offered for import by an importer identified on the Red List of this import alert, for the food identified on the Red List." If FDA field staff choose to detain an article that is included on an import alert, then the importer has the opportunity to present evidence that the shipment is in compliance. *See* section 801(a) of the FD&C Act. In other words, detention marks the beginning of the administrative process, rather than the end. The importer has the opportunity to contest the detention through the administrative process discussed above before FDA makes any final determination to refuse admission. In addition, the importer has the opportunity to provide FDA with evidence that placement on the import alert is no longer justified.[12]

In sum, being listed on an import alert does not lead to the inability to import product and there is an established process for removal from the import alert outside of the petition process (see below, footnote 13). For these reasons, the Petition's claim regarding irreparable injury does not suffice.

Additionally, for the reasons discussed in section II above, we determine that the delay resulting from a stay in this case is outweighed by public health or other public interests. Accordingly, the Petition has not satisfied the requirements of 21 CFR § 10.35(e) to require FDA to grant a stay.

IV. Discretionary Relief

Both petitions for stay and reconsideration may be granted on a discretionary basis. As to stays, "[t]he Commissioner may grant a stay in any proceeding if it is in the public interest and in the interest of justice." 21 CFR § 10.35(e). As to reconsideration, "[t]he Commissioner may grant the petition when the Commissioner determines it is in the public interest and in the interest of justice." 21 CFR § 10.33(d).

The Petition has not established that a stay or reconsideration would cure any procedural unfairness or promote the public health. There is an established procedure that JR Imports and any similarly situated firm should follow to be in compliance or come into compliance with FDA's regulations, including instructions in Import Alert #99-41 for requesting removal from the alert.[13] As explained above, in the interest of promoting public health, FDA appropriately determined that JR Imports was not in compliance with the FSVP requirements with respect to multiple imported foods and foreign suppliers specifically listed in Import Alert #99-41. See 21

[12] We note that the Petition did not provide evidence to demonstrate compliance or that placement on the import alert was no longer justified.

[13] To request removal from the Red List of this import alert, the importer or representative thereof should submit information supporting their request to the FDA Compliance officer or office identified that issued the regulatory letter notifying the importer of their FSVP violations and placement on Import Alert #99-41. The importer should submit information to adequately demonstrate that the importer has resolved the conditions that gave rise to the appearance of the FSVP violation. Such information may include information relevant to the violations described in the regulatory letter. Submissions must be in English.
The purpose of this is to provide FDA with assurance that the importer is meeting the requirements of FSVP for future entries of the food from the foreign supplier. As appropriate, FDA may conduct follow-up inspection of the importer to determine whether the appearance of the FSVP violation has been overcome.
Divisions should encourage importers to request removal from Import Alert #99-41 prior to attempting to import a specific food or all food from the specific foreign supplier listed on the Red List of this import alert. Import Alert #99-41 at 2.

CFR § 1.514(a). Granting this petition would circumvent the existing process, which is designed to ensure procedural fairness and to promote public health.

In addition, the Petition alleges that FDA deprived JR Imports of an opportunity to address alleged deficiencies, and that FDA failed to provide specific feedback and articulate a basis for its actions. The Petition also alleges that FDA exceeded its statutory authority. The record demonstrates that FDA provided JR Imports with multiple opportunities to address identified deficiencies and received and considered multiple submissions of information from JR Imports. These submissions provided JR Imports an opportunity to demonstrate to FDA that it had addressed deficiencies. FDA's May 13, 2024, "Detention Without Physical Examination Letter" to JR Imports explains why FDA found violations during inspections and why certain responses and corrective actions from JR Imports were not sufficient to address the violations. Finally, FDA is acting within its statutory authority under sections 801 and 804a of the Act (21 U.S.C. §§ 381 and 384a, respectively).

We decline to exercise FDA's discretion to grant the Petition for stay and reconsideration on the basis that the Petition is moot to the extent it requests a stay and that the Petition has not established that a stay or reconsideration would be in the public interest and the interest of justice.

V. Conclusion

For the reasons discussed above, in accordance with 21 CFR §§ 10.33 and 10.35, FDA denies your petition.

Sincerely,

Michael C. Rogers, MS
Associate Commissioner for Inspections and Investigations