U.S. FOOD & DRUG ADMINISTRATION

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Via Email
Return Receipt Requested

August 7, 2026

Mr. Dipen Patel
Chief Executive Officer
Neeyaan LLC
4 Corporate Drive
Cranbury, NJ 08512

Dear Mr. Patel:

The United States Food and Drug Administration (FDA) inspected your drug manufacturing facility, Neeyaan LLC, FEI 3024366553, at 4 Corporate Drive, Cranbury, NJ 08512 from January 13 to 27, 2026.

This letter summarizes violations of Current Good Manufacturing Practice (CGMP) regulations for finished pharmaceuticals. See Title 21 Code of Federal Regulations (CFR), parts 210 and 211 (21 CFR parts 210 and 211).

Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your drug products are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B). Manufacture, processing, packing, or holding of a drug product includes packaging and labeling operations, testing, and quality control of drug products (21 CFR 210.3(b)(12)).

Section 801(e)(1) of the Act provides an exemption for drugs intended for export that would otherwise be deemed adulterated or misbranded, provided that the requirements of that section are met. During the inspection, your firm failed to produce records demonstrating that the export requirements of section 801(e)(1) of the FD&C Act (21 U.S.C. 381(e)(1)) and the associated recordkeeping requirements established at 21 CFR 1.101(b)(1)–(4) were met. Because your firm failed to demonstrate that it meets these requirements, the export exemption does not apply. Accordingly, introducing or delivering these products for introduction into interstate commerce is prohibited under section 301(a) of the FD&C Act, 21 U.S.C. 331(a). These violations are described in more detail below.

In addition, based on our review, your firm is not currently registered and is not assigned a labeler code, which is required to list drugs. You failed to provide drug listing information for your drugs (b) (4) ,(b) (4) as required under section 510 of the FD&C Act. Failure to register and provide listing information for a drug in accordance with section 510 of the FD&C Act is prohibited under section 301(p) of the FD&C Act, 21 U.S.C. 331(p). Furthermore, these drugs are misbranded under section 502(o) of the FD&C Act, 21 U.S.C 352(o).

We reviewed your February 18, 2026, response to our Form FDA 483 in detail.

During our inspection, our investigator observed specific violations including, but not limited to, the following.

1. **Your firm failed to establish adequate written procedures for production and process control designed to assure that drug products you manufacture have the identity, strength, quality, and purity they purport or are represented to possess, and to follow all of your written production and process control procedures (21 CFR 211.100(a) and 211.100(b)).**

   You failed to demonstrate your drug manufacturing processes are adequately validated. For example, during the inspection, we observed drums containing a (b) (4) intended for the manufacturing of (b) (4) tablets, in the (b) (4) room. Your firm stated that (b) (4) operations were halted due to issues with tablet sticking and breaking. When asked for process validation data, you stated that it had not been conducted.

   Additionally, you manufactured and released (b) (4) lots of (b) (4) USP (b) (4) tablets in 2025 intended for export. Your firm stated that no process validation was conducted for this product.

   In your response, you included a statement that you will perform process validation studies on 3 batches of (b) (4) tablets, USP (b) (4). Additionally, you provided a protocol to perform a bulk hold time study for a previous manufactured batch of (b) (4) tablets, and its associated (b) (4)

   Your response is inadequate because your protocol for bulk hold time studies for (b) (4) (b) (4) tablets did not include the manufacturing process, the selection of batches, or tests designed to assess the homogeneity of the (b) (4) over the proposed time period. Additionally, your response is incomplete in that it did not include a protocol for the proposed process validation of (b) (4) tablets, USP (b) (4).

   Process validation evaluates the soundness of design and state of control of a process throughout its lifecycle. Each significant stage of a manufacturing process must be designed appropriately and assure the quality of raw material inputs, in-process material, and finished drugs. Process qualification studies determine whether an initial state of control has been established. Successful process qualification studies are necessary before commercial distribution. Thereafter, ongoing vigilant oversight of process performance and product quality is necessary to ensure you maintain a stable manufacturing operation throughout the product lifecycle.

   See FDA's guidance document *Process Validation: General Principles and Practices* for general principles and approaches that FDA considers appropriate elements of process validation at https://www.fda.gov/media/71021/download.

   Lack of Cleaning Validation

Your cleaning validation procedure requires that you develop validation protocols and reports to ensure adequate cleaning and to prevent cross-contamination. During the inspection, you stated that you had not conducted cleaning validation studies for your non-dedicated equipment to prevent cross-contamination between drug products and dietary supplements manufactured on the same equipment. Additionally, deficiencies in your cleaning program were noted including, but not limited to, inadequate detail in cleaning procedures and inconsistent documentation of cleaning.

In your response, you provided a protocol to perform clean and dirty hold time studies for your (b) (4) equipment. Your response is inadequate as the protocol fails to include the selection of batches to represent worst case (e.g., products with lower solubility) and swabbing of scientifically justified sampling points for chemical or cleaning residue with acceptance limits.

In response to this letter, provide:

- A detailed summary of your validation program for ensuring a state of control throughout the product lifecycle, along with associated procedures. Describe your program for process performance qualification, and ongoing vigilant monitoring of both intra-batch and inter-batch variation to ensure a continuing state of control. Also, describe your equipment and facility qualification program.

- A timeline for performing process performance qualification (PPQ) for each of your distributed drug products. Also provide a risk assessment and any follow-up actions to be taken for the distributed drug products produced without performing any process validation studies.

- Process performance protocol(s), and written procedures for qualification of equipment and facilities.

- A comprehensive assessment of your cleaning effectiveness to evaluate the scope of cross-contamination hazards. The assessment should identify any inadequacies of cleaning procedures and practices and encompass each piece of manufacturing equipment used to manufacture more than one product.

2. Your firm failed to test samples of each component for identity and conformity with all appropriate written specifications for purity, strength, and quality (21 CFR 211.84(d)(1) and 211.84(d)(2)).

Your firm manufactures over-the counter (OTC) drug products without adequate assurance of the quality of raw materials. For example, you did not routinely test incoming components, such as your active pharmaceutical ingredients (API) (e.g., (b) (4) USP), for identity before using them in the manufacture of your drug products. Additionally, you relied on your suppliers' certificate of analysis (COA) without establishing the reliability of each of your suppliers' analyses at appropriate intervals.

Without adequate testing, you do not have scientific evidence that your raw materials, including but not limited to active pharmaceutical ingredients, conform to the appropriate specifications before their use in the manufacture of your drug products. As a manufacturer, you are responsible for sampling, testing, and examining drug components before their use in production to ensure adequate quality.

In your response, you stated you would revise procedures related to vendor qualification to define the minimum lots for testing, require identity testing for each incoming lot, and specify the analytical testing required. However, your response did not provide adequate detail to communicate your proposed changes (e.g. number of lots to be tested, procedural details for vendor qualification, and adequacy of controls for incoming materials).

In your response, provide:

- A comprehensive, independent review of your material system, including but not limited to:
    - evaluating all suppliers of materials (components, containers, and closures) to determine if they are reliable and appropriately qualified.
    - an assessment of all materials to determine whether they are consistently of acceptable quality.
    - a review to ensure assigned expiration or retest dates are appropriate (supported by data).
    - adequacy of the supplier qualification program, and its selection, qualification, and disqualification provisions.
- Based on a thorough review, provide a summary of your CAPA to remediate the vendor qualification program and prevent use of unsuitable components, containers and closures.

3. Your firm's quality control unit failed to exercise its responsibility to ensure drug products manufactured are in compliance with CGMP, and meet established specifications for identity, strength, quality, and purity (21 CFR 211.22).

Your quality unit (QU) did not adequately exercise its authority and responsibilities including, but not limited to, implementing effective procedures and conducting adequate oversight of the drug products you manufacture. For example, your QU failed to ensure:

- Batch records contain complete information (e.g., missing drug product lot numbers (for repacking) and raw material lot numbers in batch records) (21 CFR 211.188(a)(3)).
- Establishment of written procedures to ensure traceability of raw materials and in-process materials and drug products (e.g., repackaged drug products were assigned lot

numbers that were not traceable to the purchased bulk drug products) (21 CFR 211.22(d)).

- Maintenance of distribution records (21 CFR 211.196).

- Establishment of and adherence to an adequate stability program (21 CFR 211.166(a)).

Your response is inadequate because it fails to address the systemic quality deficiencies identified during the inspection. The observed lapses indicate fundamental weaknesses in the QU's oversight function. The proposed corrective actions do not adequately demonstrate how you will strengthen quality oversight to ensure ongoing compliance with CGMP requirements.

These failures demonstrate that your quality control unit did not fulfill its fundamental responsibility to ensure that your manufacturing operations comply with CGMP requirements and that your drug products meet appropriate quality standards. See FDA's guidance document *Quality Systems Approach to Pharmaceutical CGMP Regulations* to ensure drug safety at https://www.fda.gov/media/71023/download.

In your response, provide:

- A comprehensive assessment and remediation plan to ensure your QU is given the authority and resources to effectively function. The assessment should also include, but not be limited to:

    - A determination of whether procedures used by your firm are robust and appropriate.

    - Provisions for QU oversight throughout your operations to evaluate adherence to appropriate practices.

    - A complete and final review of each batch and its related information before the QU disposition decision.

    - Oversight and approval of investigations and discharging of all other QU duties to ensure identity, strength, quality, and purity of all products.

- A comprehensive assessment and CAPA plan to ensure the adequacy of your stability program. Your remediated program should include, but not be limited to:

    - Stability indicating methods.

    - Stability studies for each drug product in its marketed container-closure system before distribution is permitted.

- An ongoing program in which representative batches of each product are added each year to the program to determine if the shelf-life claim remains valid.

- Detailed definition of the specific attributes to be tested at each station (timepoint), as part of a program that encompasses each quality attribute that may change over the product shelf-life.

- All procedures that describe these and other elements of your remediated stability program.

Manufacturing Drugs for Export

As described above, your drugs, including the (b) (4) USP (b) (4) tablets observed during the inspection, intended for export, are adulterated within the meaning of section 501(a)(2)(B) and misbranded under section 502(o) of the FD&C Act. Exporting adulterated or misbranded products is prohibited under section 301(a) of the FD&C Act.

Section 801(e)(1) of the FD&C Act provides a limited exemption from the adulteration and misbranding of exported drugs if the statutory conditions are met and are documented as specifically described at 21 CFR 1.101(b). Under 21 CFR 1.101(b)(1)–(4), persons exporting articles under or subject to section 801(e)(1) of the FD&C Act must maintain records demonstrating compliance with the statutory export requirements. These records must be retained for the same period of time as required for records subject to good manufacturing practice or quality systems regulations applicable to the product and must be made available to FDA upon request during an inspection for review and copying.

During the inspection, your firm stated that your OTC drug product manufacturing is limited to the export market only. When we requested shipping documentation for (b) (4) USP (b) (4) to verify the distribution of exported products, your firm provided a packing slip for (b) (4) (b) (4) USP (b) (4) Tablet Lot (b) (4) indicating shipment to (b) (4) and a packing slip for (b) (4) USP (b) (4) Tablet Lot # (b) (4) indicating shipment from Cranbury, NJ to (b) (4) with no specific destination address. Your firm later confirmed that, as a practice, it does not retain shipping documents and that no other shipping documents for these batches exist.

The packing slips produced during the inspection do not demonstrate compliance with the recordkeeping requirements at 21 CFR 1.101(b)(1)–(4) which are required for products exported under or subject to 801(e)(1) of the FD&C Act. Specifically, records must demonstrate that: your drug products meet the foreign purchaser's specifications, your drug products do not conflict with the laws of the importing country, the outside of shipping packages are labeled indicating the products are intended for export, and that your products were not sold or offered for sale in the United States.

Because you failed to establish and maintain the records required under 21 CFR 1.101(b)(1)–(4) to demonstrate compliance with section 801(e)(1) of the FD&C Act, your firm does not meet the conditions for this exemption. Therefore, your exported products remain adulterated and misbranded as described above and cannot be exported. Introducing or delivering these

adulterated and misbranded products into interstate commerce is a prohibited act under section 301(a) of the FD&C Act.

Establishment Registration and Drug Listing Violations

Section 510 of the FD&C Act, 21 U.S.C. 360, and 21 CFR Part 207 set forth the requirements for establishment registration and drug listing. Under section 510(c) of the FD&C Act and 21 CFR 207.17(a) firms engaged in drug manufacturing, including packaging, must be registered with FDA. Additionally, section 510(b) of the FD&C Act and 21 CFR 207.29(b) require annual review and updates of registration information for all manufacturing establishments. Your establishment was de-registered on November 26, 2025, but did not cease its manufacturing and contract packaging activities.

Section 510(j) of the FD&C Act and 21 CFR 207.41(a) require that a registrant list each drug that it manufactures for commercial distribution. Under 21 CFR 207.33(c)(1), each person who engages in manufacturing of a drug subject to listing must apply for an NDC labeler code. You failed to obtain a labeler code and list the drugs that you manufacture using that labeler code. Additionally, under 21 CFR 207.41(c)(1), a registrant must list each drug it manufactures for commercial distribution under the trade name or label of a private label distributor (PLD) using an NDC that includes such PLD's labeler code. You packaged the drugs (b) (4) (b) (4) mg (Lot (b) (4) mg (Lot (b) (4), and (b) (4) mg (Lot (b) (4) for private label distribution but you failed to list these drugs under the PLD's labeler code.

Therefore, your firm has failed to fulfill its establishment registration and drug listing obligations in accordance with section 510 of the FD&C Act. Failure to provide listing information for a drug in accordance with 510(j) of the FD&C Act is prohibited under section 301(p) of the FD&C Act. Under section 502(o), a drug is misbranded if it was manufactured in an establishment not duly registered under section 510, or if it was not included in a list required by section 510(j). Under section 301(a), it is a prohibited act to introduce or deliver for introduction into interstate commerce any drug that is misbranded.

Complete, accurate, and up-to-date establishment registration and drug listing information is essential to promote and protect patient safety. FDA relies on establishment registration and drug listing information for several key programs, including drug establishment inspections, supply chain security, and post-market surveillance. Establishment registration and drug listing information is also widely used outside FDA for purposes such as electronic prescribing and electronic health records, insurance reimbursement, and patient education.

It is your responsibility to ensure that all drugs manufactured at your establishment comply with all establishment registration and drug listing requirements under section 510 of the FD&C Act, 21 U.S.C. 360, 21 CFR Part 207, and all other applicable FDA regulations. Registration and listing information and instructions on how to properly register an establishment or submit drug listings can be found at https://www.fda.gov/drugs/electronic-drug-registration-and-listing-system-edrls/drug-registration-and-listing-instructions.

CGMP Consultant Recommended

Based upon the nature of the violations we identified at your firm, you should engage a consultant qualified as set forth in 21 CFR 211.34 to assist your firm in meeting CGMP requirements. Your use of a consultant does not relieve your facility's obligation to comply with CGMP. Your facility's executive management remains responsible for resolving all deficiencies and systemic flaws to ensure ongoing CGMP compliance.

Conclusion

The violations cited in this letter are not intended to be an all-inclusive list of violations that exist at your facility. You are responsible for investigating and determining the causes of any violations and for preventing their recurrence or the occurrence of other violations.

This letter notifies you of our findings and provides you an opportunity to address the above deficiencies. After you receive this letter, respond to this office in writing within 30 working days. Specify what you have done to address any violations and to prevent their recurrence. In response to this letter, you may provide additional information for our consideration as we continue to assess your activities and practices. If you cannot complete corrective actions within 30 working days, state your reasons for delay and your schedule for completion.

Send your electronic reply to CDER-OC-OMQ-Communications@fda.hhs.gov. Identify your response with FEI 3024366553 and ATTN: Maria Pavco.

Sincerely,

/s/
Jill P. Furman, JD
Director
Office of Compliance
Center for Drug Evaluation and Research