



U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations I
10 Waterview Blvd 3rd FL
Parsippany, NJ 07054
Telephone: (973) 331-4900
Fax: (973) 331-4969
www.fda.gov

VIA UPS

January 24, 2018

CMS # 542205

John W. Platt
Owner and Pharmacist-in-Charge
J.W. Platt, RPh LLC
dba The Wellness Pharmacy
2228 Papermill Road, Suite E
Winchester, VA 22601-3681

Dear Mr. Platt:

From May 10, 2017, to May 16, 2017, U.S. Food and Drug Administration (FDA) investigators inspected your facility, **J.W. Platt, RPh LLC**, dba **The Wellness Pharmacy**, located at 2228 Papermill Road, Suite E, Winchester, VA 22601-3681. **During the inspection, the investigators noted that drug products you produced failed to meet the conditions** of section 503A of the Federal Food, Drug, and Cosmetic Act (FDCA) [21 U.S.C. § 353a] for exemption from certain provisions of the FDCA.

FDA issued a Form FDA 483 to your firm on May 16, 2017. Based on this inspection, it appears your firm is producing drugs that violate the FDCA.

Compounded Drug Products Under the FDCA

Section 503A of the FDCA describes the conditions under which human drug products compounded by a licensed pharmacist in a State licensed pharmacy or a Federal facility, or a licensed physician, qualify for exemptions from three sections of the FDCA: compliance with current good manufacturing practices (CGMP) (section 501(a)(2)(B)); labeling with adequate directions for use (section 502(f)(1)); and FDA approval prior to marketing (section 505) [21 U.S.C. §§ 351(a)(2)(B), 352(f)(1) and 355(a)].¹ Receipt of valid prescriptions for individually-identified patients is one of the conditions for the exemptions under section 503A.

Failure to Meet the Conditions of Section 503A

¹ We remind you that there are conditions other than those discussed in this letter that must be satisfied to qualify for the exemptions in section 503A of the FDCA.

During the inspection, FDA investigators noted that drug products produced by your firm failed to meet the conditions of section 503A. For example, the investigators noted your firm did not receive valid prescriptions for individually-identified patients for a portion of the drug products you produced.

Therefore, you compounded drug products that do not meet the conditions of section 503A and are not eligible for the exemptions from the FDA approval requirement of section 505 of the FDCA, the requirement under section 502(f)(1) of the FDCA that labeling bear adequate directions for use, and the requirement of compliance with CGMP under section 501(a)(2)(B) of the FDCA. In the remainder of this letter, we refer to your drug products that do not qualify for exemptions under section 503A as the “ineligible drug products.”

Specific violations are described below.

Violations of the FDCA

Misbranded Drug Products

The ineligible drug products you compounded are intended for conditions not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layman can use these products safely for their intended uses. Consequently, their labeling fails to bear adequate directions for their intended uses.² Accordingly, these ineligible drug products are misbranded under section 502(f)(1) of the FDCA. It is a prohibited act under section 301(k) of the FDCA [21 U.S.C. § 331(k)] to do any act with respect to a drug, if such act is done while the drug is held for sale after shipment in interstate commerce and results in the drug being misbranded.

Corrective Actions

As explained above, receipt of valid prescriptions for individually-identified patients is a condition of section 503A, which your firm failed to meet for a portion of the drug products you produced. Should you continue to compound and distribute drug products that do not meet the conditions of section 503A, the compounding and distribution of such drugs would be subject to the new drug approval requirement, the requirement to label drug products with adequate directions for use, and drug CGMP requirements.

Conclusion

The violations cited in this letter are not intended to be an all-inclusive statement of violations at your facility. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA regulations.

Within thirty (30) working days of receipt of this letter, please notify this office in writing if you have taken any steps to correct the violations. Please include an explanation of each step being taken to prevent the recurrence of the violations, as well as copies of related documentation. If you do not believe that the products discussed above are in violation of the FDCA, include your reasoning and any supporting information for our consideration. If you cannot complete corrective action within thirty (30) working days, state the reason for the delay and the time within which you will complete the correction.

² Your ineligible drug products are not exempted from the requirements of section 502(f)(1) of the FDCA by regulations issued by the FDA (see, e.g., 21 CFR 201.115).

Please address your reply to:

Ernest F. Bizjak
Compliance Officer, OPQ Div. 1
FDA
11919 Rockville Pike
Rockville, MD 20852

If you have questions regarding the contents of this letter, please contact Ernest Bizjak via phone at 301-796-4081 or via email at ernest.bizjak@fda.hhs.gov.

Sincerely,

Diana
Amador-toro
-S

Digitally signed by Diana Amador-toro -S
DN: c=US, o=U.S. Government,
ou=HHS, ou=FDA, ou=People,
0.9.2342.19200300.100.1.1=130001
1579, cn=Diana Amador-toro -S
Date: 2018.01.24 11:04:54 -05'00'

Diana Amador Toro
Division Director/OPQ Division 1
New Jersey District Office