Perry Drug Inc. 2/3/15

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Kansas City District
8050 Marshall Drive, Suite 205
Lenexa, KS 66214

Telephone: (913) 495-5100
FAX: (913) 495-5115

February 3, 2015

WARNING LETTER

UNITED PARCELSERVICE
Deliverv Signature Requested

Ref: CMS #449326

Dena K. Perry, Owner/Pharmacistin Charge
Perry Drug, Inc.
12200 W. 106th Street
Suite 140 Medical Plaza West Building
Overland Park, Kansas 66215

Dear Ms. Perry:

From August 26, 2014, to August 29, 2014, and from September 4, 2014, to

September 9, 2014, a U.S. Food and Drug Administration (FDA) investigator conducted an inspection of your facility, Perry Drug, Inc., located at 12200 W. 106th Street, Overland Park, Kansas. During the inspection, the investigator observed serious deficiencies in your practices for producing sterile drug products, which put patients at risk. For example, materials and components are not disinfected before introduction into the ISO 5 area. The investigator also observed an operator processing sterile drug products wearing non-sterile gloves, with exposed skin on her nose, and wearing makeup. In addition, environmental monitoring (e.g., personnel, surface, and viable air) has not been performed. Moreover, your firm does not monitor pressure differentials throughout the day, especially during periods of production. Furthermore, the investigator found that your firm failed to demonstrate through appropriate studies that your hoods are able to provide adequate protection of the ISO 5 area in which sterile products are processed. Therefore, your products may be produced in an environment that poses a significant contamination risk. FDA issued a Form FDA 483 to your firm on September 9, 2014.

The investigator also noted that your firm produces domperidone drug products. Domperidone is not the subject of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph, nor is it a component of an FDA-approved human drug product, and it does not appear on a list developed by the Secretary under 503A(b)(1)(A)(i)(III) of the Federal Food, Drug, and Cosmetic Act (FDCA) [21 U.S.C. § 353a(b)(1)(A)(i)(III)].

Based on this inspection, it appears you are producing drugs that violate the FDCA.

A. Compounded Drugs under the FDCA

Section 503A of the FDCA [21 U.S.C. § 353a] describes the conditions under which certain compounded human drug products are entitled to exemption from three sections of the FDCA: compliance with current good manufacturing practices (CGMP) (section 501(a)(2)(B) of the FDCA [21 U.S.C. § 351(a)(2)(B)]); labeling with adequate directions for use (section 502(f)(1) of the FDCA [21 U.S.C.§ 352(f)(1)]); and FDA approval prior to marketing (section 505 of the FDCA [21 U.S.C. § 355]).

During the FDA inspection, the investigator observed that your firm produces drug products with domperidone. Compounded drug products containing domperidone are not eligible for the exemptions under section 503A of the FDCA because domperidone is not the subject of an applicable USP or NF monograph, is not a component of an FDA-approved human drug, and it does not appear on a list of bulk drug substances that may be used for compounding developed by the Secretary. Accordingly, the drug products that you compound using domperidone are not entitled to the exemptions in section 503A of the FDCA.

In addition, we remind you that there area number of other conditions that must be

satisfied to qualify for the exemptions in section 503A of the FDCA.***1***

B. Violations of the FDCA

Because the domperidone drug products that you manufacture and deliver for introduction into interstate commerce are not the subject of approved applications, they are unapproved new drugs in violation of section 505(a) of the FDCA. Furthermore, the domperidone drug products that your firm manufactures and distributes are misbranded drugs in violation of section 502(f)(1) of the FDCA, regardless of whether they are distributed in interstate commerce. In addition, your sterile drug products are prepared, packed, or held under insanitary conditions where by they may have been contaminated with filth, or whereby they may have been rendered injurious to health. As such, all sterile drug products you manufacture are adulterated within the meaning of section 501(a)(2)(A) of the FDCA [21 U.S.C.§ 351(a)(2)(A)].

Unapproved New Drug Products

You do not have any FDA approved applications on file for the drug products that you produce from bulk domperidone, which is not permitted to be used in compounding under section 503A.***2*** Under sections 505(a) and 301(d) of the FDCA [21 USC §§ 355(a) and 331(d)], a new drug may not be introduced into or delivered for introduction into interstate commerce unless an application approved by FDA under section 505 of the FDCA is in effect for the drug. Your marketing of these products, or other applicable products, without an approved application violates these provisions of the FDCA.

Misbranded Drug Products

Additionally, because the domperidone drug products are intended for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners, adequate directions cannot be written for them 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, causing them to be misbranded under section 502(f)(1) of the FDCA, and they are not exempt from the requirements of section 502(f)(l) of the FDCA *[see, e.g.,* 21 CFR 201.115]. The introduction or delivery for introduction into interstate commerce of these products therefore violates section 301(a) of the FDCA [21 USC § 331(a)]. It is also 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.

Adulterated Drug Products

Additionally, the FDA investigator observed that your sterile drug products were prepared, packed, or held under insanitary conditions, whereby they may have become contaminated with filth or rendered injurious to health, causing your drug products to be adulterated under section 501(a)(2)(A) of the FDCA. For example, materials and components are not disinfected before introduction into the ISO 5 area. The investigator also observed an operator processing sterile drug products wearing non-sterile gloves, with exposed skin on her nose, and wearing makeup. In addition, environmental monitoring (e.g. personnel, surface, and viable air) has not been performed. Moreover, your firm does not monitor pressure differentials throughout the day, especially during periods of production. Furthermore, the investigator found that your firm failed to demonstrate through appropriate studies that your hoods are able to provide adequate protection of the ISO 5 area in which sterile products are processed. Therefore, your products may be produced in an environment that poses a significant contamination risk.

Under section 301(a) of the FDCA, the introduction or delivery for introduction into interstate commerce of any drug that is adulterated is a prohibited act. Further, it is a prohibited act under section 301(k) of the FDCA 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 adulterated.

C. Corrective Actions

FDA acknowledges your voluntary recall of all aseptically filled sterile products within expiry produced from October 4, 2014, to November 3, 2014, and your action to cease compounding all sterile products on November 4, 2014. We also acknowledge receipt of your response to the Form FDA 483, dated September 30, 2014, in which you state that your firm "will compound only pursuant to prescriptions for individually identified patients" and that your firm will "adhere to state law and USP <795> and <797> guidelines for compounding of sterile and non-sterile drug products."

Please be aware that section 501(a)(2)(A) of the FDCA concerning insanitary conditions applies regardless of whether the drugs are compounded and distributed after receipt of a prescription for an identified individual patient. In addition, should you continue to manufacture and distribute domperidone drug products or should you distribute drug products without valid prescriptions for individually-identified patients, the manufacture of such drugs would be subject to FDA's drug CGMP regulations (21 CFR Parts 210 and 211), among other requirements described above, and, before doing so, you should fully implement corrections that meet the minimum requirements of 21 CFR Part 211 in order to provide assurance that the drug products produced by your firm conform to the basic quality standards that ensure safety, identity, strength, quality, and purity.

FDA strongly recommends your management immediately undertake a

comprehensive assessment of your operations, including facility design, procedures, personnel, processes, materials, and systems. In particular, this review should assess your aseptic processing operations. A third party consultant with relevant sterile drug manufacturing expertise could be useful in conducting this comprehensive evaluation. You must correct all insanitary conditions at your firm before you resume operations. We note that you state in your response to FDA Form 483 that you are in the process of retaining a consultant with expertise in aseptic processes and procedures for compounded preparations.

In addition, you should correct the violations of FDCA sections 502(f)(1) and 505(a), noted above.

D. 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 your firm complies with all requirements of federal law and FDA regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction. FDA may re-inspect to ensure that your firm complies with all requirements of federal law and FDA regulations.

Within fifteen (15) working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct violations. Please include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you do not believe 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 actions within fifteen (15) working days, state the reason for the delay and the time within which you will complete the correction. In addition to taking appropriate corrective actions, you should notify this office prior to resuming production of any sterile drugs in the future. Your written response should be sent to:

Amy Devine
Compliance Officer
U.S. Food and Drug Administration
8050 Marshall Drive, Suite 205
Lenexa, KS 66214

If you have any questions regarding any issues in this letter, please contact Ms. Devine at (913) 495-5147 or via email at amy.devine@fda.hhs.gov.

Sincerely,
/S/
Cheryl A. Bigham
Kansas City District Director

cc: Debra Billingsley, Executive Director
Kansas State Board of Pharmacy
800 SW Jackson, Suite 1414
Topeka, Kansas 66612

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1 For example, section 503A also addresses anticipatory compounding, which includes compounding (not distribution) before receipt of a valid prescription order for an individual patient. We are not addressing anticipatory compounding here.

2 The specific products made by your firm are drugs within the meaning of section 201(g) of the FDCA [21 U.S.C. § 321(g)] because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases. Further, they are "new drugs" within the meaning of section 201(p) of the FDCA [21 U.S.C. § 321(p)] because they are not generally recognized as safe and effective for their labeled uses.

More in Compliance Actions and Activities

Warning Letters

2015

2014

2013

2012

2011

2010

2009

2008

2007

2006

2005

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