WARNING LETTER

Quimica Magna de Mexico, S.A. de C.V.

MARCS-CMS 608751 — OCTOBER 15, 2020

Delivery Method:

VIA UPS

Product:

Drugs

Recipient:

Mr. Jorge Varela

CEO

Quimica Magna de Mexico, S.A. de C.V.

Telares No. 130
La Aurora 25298 Saltillo, Coah.
Mexico

Issuing Office:

Center for Drug Evaluation and Research | CDER

United States

Warning Letter 320-21-02

October 15, 2020

Dear Mr. Varela:

Your firm was recently registered as a human drug manufacturer. The U.S. Food and Drug Administration (FDA) conducted testing of consumer antiseptic drug products labeled as Datsen Hand Sanitizer and Alcohol Antiseptic 62% Topical Solution Hand Sanitizer. The Datsen Hand Sanitizer products were declared at the U.S. border as manufactured at your facility, Quimica Magna de Mexico, S.A. de C.V., FEI 3016681443, at Telares No. 130 La Aurora, Saltillo, and the Alcohol Antiseptic 62% Topical Solution Hand Sanitizer products were labeled as manufactured at that facility. Following an attempt to import them into the United States, the Datsen Hand Sanitizer products and Alcohol Antiseptic 62% Topical Solution Hand Sanitizer products were detained and refused admission at the border.

The results of the FDA laboratory testing of batches of these products detained at the border demonstrate that the Datsen Hand Sanitizer drug products, declared as manufactured at your facility, and the Alcohol Antiseptic 62% Topical Solution Hand Sanitizer drug products, labeled as manufactured by your facility, are adulterated within the meaning of section 501(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act or Act), 21 U.S.C. 351(c), in that their strength, purity, or quality falls below that which they purport or are represented to possess. In addition, these products are adulterated within the meaning of section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)), in that the subpotency demonstrates that the quality assurance within your facility is not functioning in accordance with Current Good Manufacturing Practice (CGMP) requirements.

In addition, your Datsen Hand Sanitizer and Alcohol Antiseptic 62% Topical Solution Hand Sanitizer drug products are unapproved new drugs introduced or delivered for introduction into interstate commerce in violation of section 505(a) of the FD&C Act, 21 U.S.C. 355(a), and are misbranded under sections 502(a) and (ee) of the FD&C Act, 21 U.S.C. 352(a) and (ee). Introduction or delivery for introduction of such products into interstate commerce is prohibited under section 301(d) and (a) of the FD&C Act, 21 U.S.C. 331(d) and (a). These violations are described in more detail below.

Adulteration Violations

Datsen Hand Sanitizer, declared as manufactured at your facility, is labeled to contain 75% v/v of the active ingredient alcohol (ethanol). However, FDA laboratory testing of batches of this product detained at the border found that the drug product contained only 15% ethanol v/v. Additionally, the drug product Alcohol Antiseptic 62% Topical Solution Hand Sanitizer, labeled as manufactured by your facility, is labeled to contain 62% v/v of the active ingredient alcohol (ethanol). However, FDA laboratory testing of batches of this product detained at the border found that the drug product contained only 50% v/v ethanol. These hand sanitizer drug products are adulterated under section 501(c) of the Act in that the active ingredient of ethanol is present at levels in the products lower than that which is declared on their labeling.

CDC recommends[1] that, if soap and water are not readily available, consumers use an alcohol-based hand sanitizer that contains not less than 60% alcohol (ethanol). This is the minimum active ingredient concentration of ethanol specified in FDA's 1994 Tentative Final Monograph for Health-Care Antiseptic Drug Products (59 FR 31402), as further amended by "Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Reopening of Administrative Record," Proposed Rule, 81 FR 42912 (June 30, 2016).

On June 16, 2020, FDA held a teleconference with you and your registered U.S. Agent, FDA Listing.com.[2] We recommended you consider removing all of your firm's hand sanitizer drug products currently in distribution to the U.S. market. Ultimately, you committed to recall all hand sanitizer drug products manufactured at your firm within expiration. However, as of the date of this letter you have yet to initiate a recall. On August 3, 2020, FDA notified the public of the subpotency of your hand sanitizer drugs products at the following website:
https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-hand-sanitizers-consumers-should-not-use (https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-hand-sanitizers-consumers-should-not-use)

In response to this letter provide the following:

• A detailed investigation into how the hand sanitizer drug products described above, which were labeled as containing 75% and 62% ethanol, in fact contained 15% and 50% ethanol, respectively.
• A list of all raw materials used to manufacture your hand sanitizer drug products, including the suppliers' names, addresses, and contact information.
• A list of all batches of any hand sanitizer drug products shipped to the United States by your firm, and a full reconciliation of all material you distributed.
• Copies of the complete batch records for all batches distributed to the U.S.
• During the teleconference on June 16, 2020, you stated you had test results showing your hand sanitizer drug products were subpotent, but yet you distributed them anyway. Please provide a complete, comprehensive, independent assessment of your quality unit, including laboratory practices and procedures related to release decisions.

The subpotency of hand sanitizer drug products declared or labeled as manufactured in your facility demonstrates that the quality assurance within your facility is not functioning in accordance with CGMP requirements under section 501(a)(2)(B) of the FD&C Act.[3]

Unapproved New Drug and Misbranding Violations

Datsen Hand Sanitizer and Alcohol Antiseptic 62% Topical Solution Hand Sanitizer are "drugs" as defined by section 201(g)(1)(B) of the FD&C Act, 21 U.S.C. 321(g)(1)(B), because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, and/or under section 201(g)(1)(C) of the FD&C Act, 21 U.S.C. 321(g)(1)(C), because they are intended to affect the structure or any function of the body. Specifically, Datsen Hand Sanitizer and Alcohol Antiseptic 62% Topical Solution Hand Sanitizer are intended for use as topical antiseptics.

Examples of claims observed on the Datsen Hand Sanitizer product label that provide evidence of the intended use (as defined in 21 CFR 201.128) of the product include, but may not be limited to, the following:

"Hand Sanitizer . . . Drug Facts . . . Purpose Antiseptic Handwash Uses For handwashing to decrease bacteria on the skin"

"Direction. . .Apply liberal amount into hand. . .Spread by rubbing hands together. . .Rub to dryness. . ."[4]

Examples of claims observed on the Alcohol Antiseptic 62% Topical Solution Hand Sanitizer product label that provide evidence of the intended use (as defined in 21 CFR 201.128) of the product include, but may not be limited to, the following:

"Hand Sanitizer . . . Drug Facts . . . Uses[s] Hand sanitizer to help reduce bacteria that potentially can cause disease."

These topical antiseptic products are "new drugs" within the meaning of section 201(p) of the FD&C Act, 21 U.S.C. 321(p), because they are not generally recognized as safe and effective (GRASE) for use under the conditions prescribed, recommended, or suggested in their labeling. New drugs may not be introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in section 505(a) of the FD&C Act, 21 U.S.C. 355(a), unless they are lawfully marketed under section 505G of the FD&C Act (which is not the case for these products, as further described below). No FDA-approved application pursuant to section 505 of the FD&C Act, 21 U.S.C. 355, is in effect for either of these drug products, nor are we aware of any adequate and well-controlled clinical studies in the published literature that support a determination that your Datsen Hand Sanitizer and Alcohol Antiseptic 62% Topical Solution Hand Sanitizer

drug products are GRASE for use under the conditions suggested, recommended, or prescribed in its labeling. Accordingly, these products are unapproved new drugs marketed in violation of sections 505(a) and 301(d) of the FD&C Act, 21 U.S.C 355(a) and 331(d).

We note that over-the-counter (OTC) topical antiseptic products had been the subject of rulemaking under FDA's OTC Drug Review. In particular, such products were addressed in a tentative final monograph (TFM) entitled "Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Health-Care Antiseptic Drug Products," Proposed Rule, 59 FR 31402 (June 17, 1994) (1994 TFM), as further amended by "Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Reopening of Administrative Record," Proposed Rule, 81 FR 42912 (June 30, 2016)(Consumer Antiseptic Rubs Proposed Rule).

Over the course of these rulemakings, benzalkonium chloride, ethyl alcohol (ethanol), and isopropyl alcohol were classified as Category III for use as active ingredients in consumer antiseptic rub products, meaning that additional safety and effectiveness data are needed to support a determination that a drug product containing one of these active ingredients would be GRASE for use as a consumer antiseptic rub. Additionally, OTC consumer antiseptic washes were addressed in "Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use," Proposed Rule, 78 FR 76444 (December 17, 2013) (Consumer Antiseptic Washes Proposed Rule) and "OTC Safety and Effectiveness of Topical Antimicrobial Drug Products for Over-the-Counter Human Use," Final Rule, 81 FR 61106 (September 6, 2016). We note that ethyl alcohol is not one of the active ingredients that was classified as Category III for use as an active ingredient in a consumer antiseptic wash. Under the Consumer Antiseptic Washes rulemaking, ethyl alcohol was determined to be ineligible for evaluation under the OTC Drug Review for use as an active ingredient in consumer antiseptic washes.

Section 505G of the FD&C Act addresses nonprescription drugs marketed without an approved application. Under section 505G(a)(3) of the FD&C Act, drugs that were classified as Category III for safety or effectiveness in a TFM that is the most recently applicable proposal or determination for such drug issued under 21 CFR Part 330 -- and that were not classified as Category II for safety or effectiveness -- are not required to have an approved application under section 505 in order to be marketed, as long as they are in conformity with the relevant conditions of use outlined in the applicable TFM, including the active ingredient, and comply with all other applicable requirements.

However, Datsen Hand Sanitizer and Alcohol Antiseptic 62% Topical Solution Hand Sanitizer do not conform to the 1994 TFM, as further amended by the 2016 Consumer Antiseptic Rubs Proposed Rule and the 2013 Consumer Antiseptic Washes Proposed Rule, nor any other TFM, proposed rule, or final rule, and do not meet the conditions under section 505G(a)(3) of the FD&C Act for marketing without an approved application under section 505.

As previously noted, statements on the Datsen Hand Sanitizer label suggest both that the product is a consumer antiseptic wash and that it is a consumer antiseptic rub. However, ethanol (in any concentration) is not an active ingredient permitted for use in consumer antiseptic hand washes under the 1994 TFM as amended by the Consumer Antiseptic Washes Proposed Rule. Moreover, antiseptic washes are outside the scope of FDA's temporary policies for hand sanitizers.

Furthermore, according to the product label, Datsen Hand Sanitizer purportedly contains the active ingredient ethanol 75% v/v, and the label of Alcohol Antiseptic 62% Topical Solution Hand Sanitizer purports that it contains the active ingredient ethanol 62% v/v. However, as previously discussed, FDA laboratory analyses of batches of these products detained at the border revealed that Datsen Hand Sanitizer contains a concentration of ethanol that is far less than the 75% v/v stated on its product label, and that Alcohol Antiseptic 62% Topical Solution Hand Sanitizer contains a concentration of ethanol that is far less than the 62% v/v stated on its product label. Both products therefore contain far less than the amount of ethanol described in the 1994 TFM.[5] Such products do not conform to the TFM and other applicable requirements, nor are they consistent with the formulations described in the guidances setting forth FDA's temporary policies for hand sanitizers during the COVID-19 public health emergency.[6]

Additionally, these hand sanitizers are misbranded under section 502(a) of the FD&C Act, 21 U.S.C. 352(a), because their labeling is false and misleading. As noted above, Datsen Hand Sanitizer and Alcohol Antiseptic 62% Topical Solution Hand Sanitizer are labeled to contain ethanol 75% v/v and 62% v/v, respectively. However, FDA laboratory analyses revealed that samples of these products contain concentrations of ethanol that is far less than what stated on their respective product labels.

Thus the misleading representations of the concentrations of the active ingredient ethanol on the Datsen Hand Sanitizer and Alcohol Antiseptic 62% Topical Solution Hand Sanitizer labeling cause these products to be misbranded under section 502(a) of the FD&C Act, 21 U.S.C. 352(a). Lastly, these products are misbranded under section 502(ee) of the FD&C Act, 21 U.S.C. 352(ee), because Datsen Hand Sanitizer and Alcohol Antiseptic 62% Topical Solution Hand Sanitizer are nonprescription drugs governed by section 505G of the FD&C Act, 21 U.S.C. 355h, but do not comply with the requirements for marketing under that section and are not the subject of an application approved under section 505 of the FD&C Act, 21 U.S.C. 355.

The introduction or delivery for introduction of a misbranded drug into interstate commerce is prohibited under section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

CGMP Consultant Recommended

Based upon the nature of the violations we identified at your firm, we strongly recommend engaging a consultant qualified, as set forth in 21 CFR 211.34, to evaluate your operations and to assist your firm in meeting CGMP requirements, if your firm intends to resume manufacturing drugs for the U.S. market. We also recommend that the qualified consultant perform a comprehensive audit of your entire operation for CGMP compliance and that the consultant evaluates the completion and efficacy of your corrective actions and preventive actions before you pursue resolution of your firm's compliance status with FDA. Your use of a consultant does not relieve your firm's obligation to comply with CGMP. Your firm'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 associated with your drug products. You are responsible for investigating and determining the causes of these violations and for preventing their recurrence or the occurrence of other violations.

Note that FDA placed all drugs and drug products manufactured by your firm on Import Alert 66-78 on July 15, 2020, as the methods used in and controls used for the manufacture, processing, packing, or holding of these products do not appear to conform to current good manufacturing practice within the meaning of section

501(a)(2)(B) of the FD&C Act. Your drugs and drug products may be subject to detention without physical examination.

All drugs and drug products manufactured by your firm may remain listed on this import alert until there is evidence establishing that the conditions that gave rise to the appearance of the violation have been resolved, and the Agency has confidence that future entries will be in compliance with the Act. This may include an inspection prior to the Agency considering the appearance of adulteration to be addressed.

If you decide you want to manufacture drugs for the United States in the future, request a Regulatory Meeting to discuss corrective actions.

After you receive this letter, respond to this office in writing within 15 working days. Specify what you have done to correct your violations and to prevent their recurrence. If you cannot complete corrective actions within 15 working days, state your reasons for delay and your schedule for completion. If you believe that your products are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration.
Send your electronic reply to CDER-OC-OMQ-Communications@fda.hhs.gov.

Please identify your response with FEI 3016681443 and ATTN: Philip Kreiter.

Sincerely,
/S/
Francis Godwin
Director
Office of Manufacturing Quality
Office of Compliance
Center for Drug Evaluation and Research

CC:
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1 https://www.cdc.gov/handwashing/hand-sanitizer-use.html

2 Under section 510(i)(1) of the FD&C Act, 21 U.S.C. 360(i)(1), you are required to submit registration information annually by electronic means for each foreign establishment you own or operate engaged in the manufacture, preparation, propagation, compounding, or processing of a drug that is imported or offered for import into the United States, and include the name of the United States Agent. On April 7, 2020, the registration for Quimica Magna identified FDAListing.com Inc. (DUNS 117011860) as the U.S. Agent. As a drug manufacturer, it is your responsibility to ensure complete and accurate registration information.

3 Due to an increased demand for alcohol-based hand sanitizers during the COVID-19 pandemic, FDA published the Guidance for Industry: Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) on March 19, 2020, and subsequently updated the guidance several times, most recently on August 7, 2020. This guidance communicates the Agency's temporary policy that we do not intend to take action against firms for CGMP violations under section 501(a)(2)(B) of the FD&C Act if such firms prepare alcohol-based hand sanitizers for consumer use (or for use as a health care personnel hand rub) during the public health emergency, provided certain circumstances described in the guidance are present. These circumstances include preparation of hand sanitizer products using only the ingredients and formulas set forth in the guidance. In addition to the violative sample results detailed above that demonstrate the subpotency of hand sanitizer products declared or labeled as manufactured at your facility, a review of the formulations on the drug products' labeling further indicates that such products are not prepared consistent with FDA's temporary policy set forth in the guidance. Therefore, these products do not fall within the Agency's temporary policy not to take action against firms manufacturing hand sanitizer products for violations of section 501(a)(2)(B) of the FD&C Act.

4 We note that your Datsen Hand Sanitizer labeling contains conflicting information regarding whether it should be used as a consumer antiseptic wash or a consumer antiseptic rub. The term "hand sanitizer" generally refers to consumer antiseptic rubs, and the Drug Facts Label of your product both indicates that the product is to be used for handwashing (presumably with water) and suggests that it should be used without water (i.e., "[a]pply liberal amount into hand" and "rub to dryness with attention to area around nails and between fingers"). The Datsen Hand Sanitizer product, however, does not conform to the requirements for either a consumer antiseptic rub or a consumer antiseptic wash, as further described below.

5 The 1994 TFM, which does not distinguish between antiseptic hand washes and rubs, proposed for antiseptic handwashes and healthcare personnel handwashes an alcohol concentration of 60 to 95% by volume in an aqueous solution: 59 FR at 31442. Later amendments to the 1994 TFM distinguished between antiseptic hand washes and rubs, and between consumer and healthcare personnel antiseptics, but did not change the alcohol concentration originally proposed in 1994.

6 See, e.g., Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19). Because Datsen Hand Sanitizer and Alcohol Antiseptic 62% Topical Solution Hand Sanitizer are not consistent with the formulations in these guidances, they do not fall within any temporary Agency policy not to take action against firms manufacturing hand sanitizer products for violations of section 505 of the FD&C Act.

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