DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

July 21, 2017

Yves Bolduc, President
Meunerie Sawyerville, Inc.
100 Rue DE LA Meunerie
Ste. 100
Cookshire-Eaton, QC J0B1M0
Canada

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
Docket No. FDA-2017-N-0901

Dear Mr. Bolduc:

This letter is to inform you that the Food and Drug Administration (FDA) is proposing to issue an order under section 306(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 335a(b)(1)(C)) debarring Meunerie Sawyerville, Inc. from importing articles of food or offering such articles for import into the United States for a period of five years. FDA bases this proposal on a finding that Meunerie Sawyerville, Inc. has been convicted, as defined in section 306(l)(1)(B) of the Act (21 U.S.C. § 335a(l)(1)(B)) of two felony counts under Federal law for conduct relating to the importation into the United States of an article of food. This letter also offers Meunerie Sawyerville, Inc. an opportunity to request a hearing on this proposal, and provides Meunerie Sawyerville, Inc. with the relevant information should Meunerie Sawyerville, Inc. wish to acquiesce to this proposed debarment.

Conduct Related to Conviction

On November 9, 2015, Meunerie Sawyerville, Inc. was convicted, as defined in section 306(l)(1)(B) of the Act (21 U.S.C. § 335a(l)(1)(B)), in the United States District Court for the District of Vermont, when the court accepted Meunerie Sawyerville, Inc.'s plea of guilty and entered judgment against Meunerie Sawyerville, Inc. for the offense of making and using a false writing that contained a materially fictitious statement in violation of 18 U.S.C. §§ 1001(a)(3) & 2, and the offense of knowingly and intentionally causing an adulterated drug to be introduced into interstate commerce in violation of 21 U.S.C. §§ 331(a), 333(a)(2), & 351(a)(6), and 18 U.S.C. §2. These offenses were related to the importation under false documentation and the introduction in interstate commerce of cow feed medicated with an unlawful amount of monensin and to the use of fictitious CFIA Export Certificates. The underlying facts supporting this conviction are as follows:

From on or about September 12, 2012, to on or about January 15, 2013, Meunerie Sawyerville knowingly and intentionally made and used a false writing, knowing the same contained a materially fictitious statement and entry in a matter within the jurisdiction of the executive branch of Government of the United States, by submitting a false Automated Commercial Environment Manifest listing a fictitious importer and presenting such documents to Customs and Border Protection officials, at Derby Line Port of Entry, Derby Line, Vermont, knowing and believing that the fictitious importer was not the true importer of the goods described in the manifest in violation of 18 U.S.C. §§ 1001(a)(3) & 2.

Additionally, from on or about September 12, 2012 to on or about January 15, 2013, Meunerie Sawyerville, Inc., with the intent to defraud and mislead, caused a drug, namely monensin, to be introduced into interstate commerce, and such drug was adulterated in violation of 21 U.S.C. §§ 331(a), 333(a)(2), & 351(a)(6), and 18 U.S.C. §2. Specifically, Meunerie Sawyerville, Inc. caused cattle feed medicated with the drug monensin at a concentration above that allowed by FDA and above the amount indicated on the feed label to be imported into the United States.

FDA's Finding

Section 306(b)(1)(C) of the Act (21 U.S.C. § 335a(b)(1)(C)) permits FDA to debar a person from importing an article of food or offering such an article for import into the United States. A person that has been convicted of a felony for conduct relating to the importation into the United States of any food may be subject to debarment under section 306(b)(1)(C), as set forth in section 306(b)(3)(A) of the Act (21 U.S.C. § 335a(b)(3)(A)). Meunerie Sawyerville, Inc.'s felony convictions were for making and using a false writing that contained a materially fictitious statement and knowingly and intentionally causing an adulterated drug to be introduced into interstate commerce. As stated above, in this case Meunerie Sawyerville, Inc.'s felony convictions were related to the importation of cattle feed medicated with the drug monensin at a concentration above that allowed by FDA and above the amount indicated on the feed label. As such, FDA finds that the felony convictions were for conduct relating to the importation into the United States of an article of food, in this case a medicated cattle feed.

This action is timely under Section 306(1)(2) of the Act (21 U.S.C.335a(1)(2)) because Meunerie Sawyerville, Inc. was convicted of making and using a false writing that contained a materially fictitious statement in violation of 18 U.S.C. §§ 1001(a)(3) & 2, and of knowingly and intentionally causing an adulterated drug to be introduced into interstate commerce in violation of 21 U.S.C. §§331(a), 333(a)(2), & 351(a)(6), and 18 U.S.C. §2 less than five years before the initiation of this action. The maximum period of debarment for each offense under section 306(c)(2)(A)(iii) of the Act (21 U.S.C. § 335a(c)(2)(A)(iii)) is five years. Section 306(c)(3) of the Act (21 U.S.C. § 335a(c)(3)) provides six factors for consideration in determining the appropriateness of and period of permissive debarment for a person. Those factors relevant to the debarment of a person for a felony conviction for conduct relating to the importation into the United States of any food are as follows:

1. the nature and seriousness of any offense involved,

2. the nature and extent of management participation in any offense involved, whether corporate policies and practices encouraged the offense, including whether inadequate institutional controls contributed to the offense,

3. the nature and extent of voluntary steps to mitigate the impact on the public of any offense involved, including . . . full cooperation with any investigations (including the extent of disclosure to appropriate authorities of all wrongdoing) . . . and any other actions taken to substantially limit potential or actual adverse effects on the public health,

4. whether the extent to which changes in ownership, management, or operations have corrected the causes of any offense involved and provide reasonable assurances that the offense will not occur in the future, and

5. prior convictions under the Act or under other Acts involving matters within the jurisdiction of the Food and Drug Administration.

FDA has determined that four of these factors are applicable for consideration:

1. Nature and seriousness of any offense involved.

Meunerie Sawyerville, Inc. pled guilty to the crimes with which it was charged, acknowledging it was in fact guilty of these crimes, as stated in the Plea Agreement filed in the United States District Court for the District of Vermont. As described above, Meunerie Sawyerville, Inc. was convicted of making and using a false writing that contained a materially fictitious statement in violation of 18 U.S.C. §§ 1001(a)(3) & 2, and of knowingly and intentionally causing an adulterated drug to be introduced into interstate commerce in violation of 21 U.S.C. §§ 331(a), 333(a)(2), & 351(a)(6), and 18 U.S.C. § 2. Meunerie Sawyerville Inc. knowingly and intentionally caused the submission of false information to United States Customs and Border Protection officials and Meunerie Sawyerville, Inc. with the intent to defraud and mislead, caused a drug, namely monensin, to be introduced into interstate commerce, and such drug was adulterated. This drug was contained in medicated cattle feed at a concentration above that allowed by FDA and above the amount indicated on the feed label.

FDA finds that Meunerie Sawyerville Inc.'s conduct undermined the integrity of FDA's regulation of the importation of food, in this case medicated cattle feed, into the United States and the introduction of such food into interstate commerce. While the Plea Agreement filed in the United States District Court for the District of Vermont states that no person suffered and identifiable loss and no public harm was caused by these offenses, FDA considers the nature of the offenses a negative factor because the actions undermined FDA's regulation of food imported into the United States. Accordingly, FDA concludes that the nature and seriousness of the conduct of Meunerie Sawyerville, Inc. supports a three-year period of debarment.

2. Nature and extent of management participation in any offense involved, whether corporate policies and practices encouraged the offense, including whether inadequate institutional controls contributed to the offense.

Yves Bolduc was the president and owner of Meunerie Sawyerville, Inc. Meunerie Sawyerville, Inc. knowingly and intentionally submitted a false writing to Customs and Border Protection officials which allowed them to import and introduce into interstate commerce medicated cow feed containing an unlawful amount of the drug monensin. From on or about September 12, 2012,

to on or about January 15, 2013 Meunerie Sawyerville, Inc. knowingly and intentionally made and used false writing, knowing the same to contain a materially fictitious statement, listing a fictitious importer, and presenting such documents to Customs and Border Protection officials, knowing and believing that the fictitious importer was not the true importer of the goods described in the manifest.

As stated in a press release issued on July 8, 2015, in connection with the relevant conduct by Meunerie Sawyerville, Inc., after the medicated feed at issue was sampled at the border, found to contain monensin at a concentration above that allowed by FDA, and the driver was ordered to warehouse the feed pending further testing from FDA, Mr. Bolduc instructed the drive to deliver the feed to a Vermont farmer as planned, without informing the farmer that the feed had been sampled and ordered held by FDA.

Mr. Bolduc then engineered a plan that a sham shipment of similar-looking cattle feed cross the border under false Customs documentation to be stored on an unrelated piece of land in Vermont until requested for redelivery by Customs and Border Protection. Upon request by Customs and Border Protection, Mr. Bolduc ordered that the sham shipment be presented for redelivery, accompanied by the fictitious documentation, offering up the sham shipment feed to the U.S. government as the held tainted feed.

Based on this information, FDA will consider this a negative factor. FDA concludes that the nature and extent of management participation in these offenses supports the maximum possible period of debarment.

3. Nature and extent of voluntary steps to mitigate the impact on the public of any offense involved.

In determining the period of a debarment, FDA is also to consider the nature and extent of voluntary steps taken to mitigate the impact on the public of any offense involved, including, among other things, full cooperation with any investigation (including the extent of disclosure to appropriate authorities of all wrongdoing) and any other actions taken to substantially limit potential or actual adverse effects on the public health. Meunerie Sawyerville, Inc. was convicted of making and using a false writing that contained a materially fictitious statement in violation of 18 U.S.C. §§ 1001(a)(3)&2, and knowingly and intentionally causing an adulterated drug, specifically a medicated cattle feed containing an unlawful amount of the drug monensin, to be introduced into interstate commerce in violation of 21 U.S.C. §§331(a), 333(a)(2), 351(a)(6), and 18 U.S.C. §2.

Meunerie Sawyerville, Inc. took no steps to mitigate the impact on the public of its actions, which undermined the integrity FDA's regulation of the importation of food, in this case medicated cattle feed, into the United States and the introduction of such food into interstate commerce.

As detailed above, the facts support the conclusion that Meunerie Sawyerville, Inc. displayed a wanton disregard for the food importation regulatory process. Accordingly, FDA will consider this a negative factor. FDA concludes that the failure to take any steps to mitigate the potential impact on the public supports the maximum possible period of debarment.

4. Prior convictions under the Act or involving matters within the jurisdiction of FDA.

FDA is unaware of any prior criminal convictions involving matters within the jurisdiction of FDA. The Agency will consider this as a favorable factor.

Proposed Action and Notice of Opportunity for Hearing

Based on the findings discussed above, FDA concludes that the facts supporting the unfavorable factors outweigh those supporting the favorable factors, and therefore warrant the imposition of a five-year period of debarment. FDA therefore proposes to issue an order under section306(b)(1)(C) of the Act (21 U.S.C. § 335a(b)(1)(C)) debarring Meunerie Sawyerville, Inc. from importing articles of food or offering such articles for import into the United States for a period of five years. Meunerie Sawyerville, Inc. was convicted of one count of making and using a false writing that contained a materially fictitious statement in violation of 18 U.S.C. §§ 1001(a)(3) & 2, and one count of knowingly and intentionally causing an adulterated drug to be introduced into interstate commerce in violation of 21 U.S.C. §§ 331(a), 333(a)(2), & 351(a)(6), and 18 U.S.C. § 2. In this case, Meunerie Sawyerville, Inc.'s felony convictions were related to the importation of cattle feed medicated with the drug monensin at a concentration above that allowed by FDA and above the amount indicated on the feed label. As such, FDA finds that the felony convictions were for conduct related to the importation into the United States of any food. In addition, based on the analysis above, FDA concludes the unfavorable factors outweigh the favorable factors. As such, FDA proposes that each felony offense be accorded a debarment period of five years. In the case of a person debarred for multiple offenses, FDA may determine whether the periods of debarment shall run concurrently or consecutively (21 U.S.C. §335a(c)(2)(A)). Given the analysis above, FDA has concluded that the five year period of debarment for each of the two felony offenses should run concurrently, resulting in a total debarment period of five years. In accordance with section 306 of the Act (21 U.S.C. § 335a) and 21 CFR part 12, Meunerie Sawyerville, Inc. is hereby given an opportunity to request a hearing to show why Meunerie Sawyerville, Inc. should not be debarred.

If Meunerie Sawyerville, Inc. decides to seek a hearing, Meunerie Sawyerville, Inc. must file the following: (1) on or before 30 days from the date of receipt of this letter, a written notice of appearance and request for hearing; and (2) on or before 60 days from the date of receipt of this letter, the information on which Meunerie Sawyerville, Inc. relies to justify a hearing. The procedures and requirements governing this notice of opportunity for hearing, a notice of appearance and request for a hearing, information and analyses to justify a hearing, and a grant or denial of a hearing are contained in 21 CFR part 12 and section 306(i) of the Act (21 U.S.C. § 335a(i)).

Meunerie Sawyerville, Inc.'s failure to file a timely written notice of appearance and request for hearing constitutes an election by Meunerie Sawyerville, Inc. not to use the opportunity for a hearing concerning Meunerie Sawyerville, Inc.'s debarment and a waiver of any contentions concerning this action. If Meunerie Sawyerville, Inc. does not request a hearing in the manner prescribed by the regulations, FDA will not hold a hearing and will issue a final debarment order as proposed in this letter.

A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. A hearing will be denied if the data and information Meunerie Sawyerville, Inc. submits, even if accurate, are insufficient to justify the factual determination urged. If it conclusively appears from the face of the information and factual analyses in Meunerie Sawyerville, Inc.'s request for a hearing that there is no genuine and substantial issue of fact that precludes the order of debarment, the Commissioner of Food and Drugs will deny Meunerie Sawyerville, Inc.'s request for a hearing and enter a final order of debarment.

Meunerie Sawyerville, Inc. should understand that the facts underlying Meunerie Sawyerville, Inc.'s conviction are not at issue in this proceeding. The only material issue is whether Meunerie Sawyerville, Inc. was convicted as alleged in this notice and, if so, whether, as a matter of law, this conviction supports Meunerie Sawyerville, Inc.'s debarment under section 306(b)(1)(C) of the Act (21 U.S.C § 335a(b)(1)(C)) as proposed in this letter.

Meunerie Sawyerville, Inc.'s request for a hearing, including any information or factual analyses relied on to justify a hearing, must be identified with Docket No. FDA-2017-N-0901 and sent to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Meunerie Sawyerville, Inc. must file four copies of all submissions pursuant to this notice of opportunity for hearing. The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Meunerie Sawyerville, Inc. also may notify the Secretary that Meunerie Sawyerville, Inc. acquiesces to this proposed debarment. If Meunerie Sawyerville, Inc. decides to acquiesce, Meunerie Sawyerville, Inc.'s debarment shall commence upon such notification to the Secretary in accordance with section 306(c)(2)(B) (21 U.S.C. § 335a(c)(2)(B)).

This notice is issued under section 306 of the Act (21 U.S.C. § 335a) and under authority delegated to the Director, Office of Enforcement & Import Operations, Office of Regulatory Affairs (FDA Staff Manual Guide 1410.35).

Sincerely,

/s/
Douglas Stearn,
Director
Office of Enforcement & Import Operations
Office of Regulatory Affairs