Shur-Green Farms 4/24/15

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700

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April 24, 2015

Warning Letter
CIN-15-449307-16

VIA UPS OVERNIGHT DELIVERY

Adam J. Kremer, Manager
Shur-Green Farms, LLC
9159 State Route 118
Ansonia, OH 45303

Dear Mr. Kremer:

From October 3, 2014 through November 19, 2014 the Food and Drug Administration conducted an inspection of your operation located at 9159 State Route 118, Ansonia, OH. Additionally, FDA collected feed samples from one of your customers. Our inspection and sample testing revealed significant violations of the Federal Food, Drug, and Cosmetic Act (the Act). Such violations caused the animal food distributed by your firm to be adulterated and misbranded as described further below. Under section 301(a) of the FD&C Act [21 U.S.C. § 331(a)] the introduction or delivery for introduction into interstate commerce of any food that is adulterated or misbranded is prohibited. You can find the FD&C Act and its implementing regulations through links on FDA's web page at http://www.fda.gov.

On December 15, 2014 we received your firm's response to the FDA Form 483 issued on November 19, 2014. This response did not adequately address our concerns regarding your distribution of adulterated and misbranded food. Specifically, your response does not address how you have remedied the observed violations or steps you have taken to prevent their recurrence.

Adulterated Animal Food

On July 8, 2013 your firm entered a contractual agreement with **(b)(4)** to collect and transport lascadoil waste from **(b)(4)**. You stated in a signed affidavit that **(b)(4)** representatives informed you that lascadoil waste is to be distributed to the biofuel industry only. Furthermore, you provided our investigator with a Material Safety Data Sheet (MSDS) that was provided to you by **(b)(4)** which states "Product Use: Fuel" This MSDS also lists the ingredients of lascadoil as oleic acid, soy oil and lascalocid sodium (an active pharmaceutical ingredient (API) used in animal drugs).

- In your affidavit, you stated that "On 09/04/14 my firm was notified by **(b)(4)**, of an ongoing FDA investigation related to Lascadoil contamination in animal feed and directed to deliver future shipments to **(b)(4)** for incineration."
- On September 11, 2014, you e-mailed **(b)(4)** with a subject line "Soyoil" and asked "Can you use this oil?" On September 11, 2014, **(b)(4)** responded and asked "Looks like human grade stuff on the analysis. What is it and what are they saying is wrong with it?" You responded "Nothing wrong with it. It's soyoil we get from a large food manufacturer. We've been selling to bio-diesel and custom blenders."
- Additional e-mails between your firm and **(b)(4)** confirm the purchase and shipment of a load to arrive on September 12, 2014. On September 12, 2014 you distributed to **(b)(4)** lascadoil containing lascalocid sodium (an API used in animal drugs) which you had represented as soy oil from a food manufacturer. The tanker used to distribute the lascadoil was tanker number 1892, which you informed the FDA investigator was one of the tankers dedicated for transport of lascadoil waste.

On September 15, 2014, you e-mailed **(b)(4)** with the subject "Re: soyoil" and said "Any interest in another load?" Additional e-mails between **(b)(4)** and you confirm the delivery of a load for that day. On September 15, 2014 you distributed to **(b)(4)** lascadoil containing lascalocid sodium (an API used in animal drugs) which you had represented as soy oil from a large food manufacturer. The tanker used to distribute the lascadoil was tanker number 3065, which you informed the FDA investigator was one of the tankers dedicated for transport of lascadoil waste.

You represented both of these shipments as “soy oil” from a large food manufacturer, implying that they were fit for use as food. However, these shipments contained lascadoil; a combination of oleic acid, soy oil, and lasalocid sodium (an API used in animal drugs). This lascadoil is a waste byproduct for fuel use only. Four samples of animal feed collected from **(b)(4)** revealed concentrations of lascalocid ranging from 0.028 to 1642 parts per million. This product was not a product to be incorporated into animal food; therefore, this lascadoil is unfit for animal food and is adulterated under 402(a)(3) of the FD&C Act [21 U.S.C. § 342(a)(3)].

In addition, the lascadoil is a food additive under section 201(s) of the Act [21 U.S. C. 321(s)] because it was intended to become a component of animal food. Lascadoil is not the subject of a food additive regulation that prescribes the conditions under which the additive may be safely used. Furthermore, we are not aware of any basis to conclude that lascadoil is generally recognized as safe (GRAS) for use in animal food. This lascadoil is a waste byproduct for fuel use only; therefore, it is adulterated under section 402(a)(2)(C)(i) of the Act [21 U.S.C. 342(a)(2)(C)(i)] because it is a food additive that is unsafe within the meaning of section 409 of the FD&C Act [21 U.S.C. § 348].

We note that the distribution described above was not the first time you distributed an adulterated animal food product. On July 30, 2014, your firm transported a load of lascadoil to **(b)(4)**. The sale load of lascadoil was brokered by **(b)(4)** and was implicated in the contamination of feed with lascalocid sodium that resulted in the loss of 57,700 turkeys. This feed contamination event also resulted in

35,900 head of swine being held from market for 29 days and the land filling of over 500 tons of withdrawn contaminated feed.

Misbranded Animal Food

Under section 201(m) of the Act, 21 U.S.C. § 321(m) "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) *accompanying such article.* On an invoice to **(b)(4)** dated 2/6/2014, you represented a shipment of lascadoil as a "soyoil blend." On invoices to **(b)(4)** dated 2/19/14, 2/24/2014, 3/20/2014, 3/21/2014 and 3/26/2014, you represented shipments of lascadoil as "used cooking oil" or "UCO." In these invoices, you represented shipments of lascadoil as soyoil and used cooking oil, when it was a combination of oleic acid, soy oil and lasalocid sodium (an API used in animal drugs) that was to be distributed for fuel use only. These invoices constitute labeling for the lascadoil pursuant to section 201(m) of the Act because they accompanied the sale of the product. As a result the lascadoil is misbranded under section 403(a)(1) of the Act [21 U.S.C. § 343(a)(1)] because its labeling is false or misleading.

In addition, we note that your customer **(b)(4)** also based their purchase of the lascadoil on the written material in your emails. In these emails you represented the lascadoil as soyoil from a large food manufacturer, when it was a combination of oleic acid, soy oil and lasalocid sodium (an API used in animal drugs) from **(b)(4)** (an animal drug manufacturer) that was to be distributed for fuel use only.

The above is not intended to be an all-inclusive list of violations. You are responsible for assuring that your overall operation and any products you distribute are in compliance with the law. You should take prompt action to correct the violations described in this letter and to establish procedures to ensure that these violations do not recur. Failure to do so may result in enforcement action without further notice such as seizure and/or injunction.

You should notify this office in writing of the steps you have taken to bring your firm into compliance with the law within fifteen (15) working days of receiving this letter. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence in your remaining animals. If corrective action cannot be completed within fifteen (15) working days of receiving this letter, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your written response should be sent to Stephen J. Rabe, Compliance Officer, U.S. Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237. If you have any questions about this letter, please contact Compliance Officer Rabe at 513-679-2700, ext. 2163 or **stephen.rabe@fda.hhs.gov (mailto:stephen.rabe@fda.hhs.gov)**.

Sincerely yours,
/S/
Douglas T. Heitkemper
Acting District Director
Cincinnati District

Cc: Rick Kremer
Kelsey Kremer