DATE: January 23, 2020

TO: Health Commissioners, Directors of Environmental Health and Interested Parties

RE: Recall Announcement (ODA/ODH) 2020-014

Public Health Alert Concerning Nopalina Flax Seed Powder and Nopalina Flax Seed Capsules and Salmonella Contamination

Purpose
The FDA is advising consumers to stop using Nopalina Flax Seed Fiber (powder) and Nopalina Flax Seed Fiber (capsules) identified by the lot numbers above due to possible Salmonella contamination. Consumers of these products who are experiencing symptoms of salmonellosis should contact their health care provider. To date, there are no reports of illnesses associated with the products.

Audience
Consumers who have purchased Nopalina Flax Seed Fiber (powder) and Nopalina Flax Seed Fiber (capsules) manufactured by Salud Natural Entrepreneur, Inc. with the specific lot numbers listed below.

Products
Nopalina Flax Seed Fiber (powder) and Nopalina Flax Seed Fiber (capsules) with lot numbers (Product Image):

Nopalina Flax Seed Fiber (powder, 1 lb. bags)
- Lot # 62.19/9#52.1 Best if used by 10/7/21
- Lot # 62.19/2#52.1 Best if used by 10/7/21

Nopalina Flax Seed Fiber (powder, 2 lb. bags)
- Lot # 64.19/2#52.1 Best if used by 10/21/21
- Lot # 64.19/2*2Lb#52.1 Best if used by 10/21/21

Nopalina Flax Seed Fiber (powder, 1 lb. bags)
- Lot # 65.19/1#52.1 Best if used by 10/24/21
- Lot # 65.19/2#52.1 Best if used by 10/24/21
Nopalina Flax Seed Fiber (capsules, 120 count)

- Lot # 23.19 1C120#07 Best if used by 10/7/21
- Lot # 23.192C120#02 Best if used by 10/7/21
- Lot # 23.19/2C120#02 Best if used by 10/7/21
- Lot # 23.19.2C120#02 Best if used by 10/7/21
- Lot # 23.19.3C120#02 Best if used by 10/7/21

The lot numbers can be found on the bottom back of the product label.

Symptoms of salmonellosis

Salmonella are a group of bacteria that can cause gastrointestinal illness and fever called salmonellosis. Most people infected with Salmonella begin developing symptoms 12 to 72 hours after infection. The illness usually lasts four to seven days and most people recover without treatment.

Most people with salmonellosis develop diarrhea, fever, and abdominal cramps. More severe cases of salmonellosis may include a high fever, aches, headaches, lethargy, a rash, blood in the urine or stool, and in some cases may become fatal.

Children younger than five, the elderly, and people with weakened immune systems are more likely to have severe salmonellosis infections.

Summary of Problem and Scope

The FDA collected a product sample of senna leaves powder, an ingredient used to manufacture the Nopalina Flax Seed Fiber (powder) and Nopalina Flax Seed Fiber (capsules), that tested positive for three types of Salmonella including Salmonella Gaminara, Salmonella Kentucky, and Salmonella Oranienburg. The FDA notified the firm of the results. To date, we are not aware of illnesses linked to these products.

FDA Actions

The FDA intends to use all available tools to remove contaminated product from the market.

Recommendations for Consumers

Consumers who have these products should no longer use them. Consumers who have symptoms of salmonellosis should contact their health care provider to report their symptoms and receive care.

To report a complaint or adverse event (illness or serious allergic reaction), you can:

- Call an FDA Consumer Complaint Coordinator if you wish to speak directly to a person about your problem.
- Report the adverse event to the FDA through the Safety Reporting Portal.

Visit www.fda.gov/fcic for additional consumer and industry assistance.