

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER

Cincinnati District Office
6751 Steger Drive
Cincinnati, OH 45237
513-679-2700

DATE(S) OF INSPECTION

10/03/2014-11/19/2014

FEI NUMBER

3011082279

Industry Information: www.fda.gov/oc/industry

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Adam J. Kremer, Manager

FIRM NAME

Shur-Green Farms, LLC

STREET ADDRESS

9159 State Route 118

CITY, STATE AND ZIP CODE

Ansonia, Ohio 45303

TYPE OF ESTABLISHMENT INSPECTED

Distributor

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1

You marketed, sold, and shipped Lascadoil waste, an industrial by-product intended for use as a bio-fuel ingredient, as an ingredient for use in animal feed mixtures. On 09/05/2014, you sent an email to your broker confirming Lascadoil could be used in animal feed.

OBSERVATION 2

You were notified of animal feed contamination related to the Lascadoil you were dealing and continued to distribute to feed manufacturers. On 09/04/2014 you were notified by your supplier of an ongoing FDA investigation due to Lascadoil contaminated feed and instructed by your supplier to incinerate the Lascadoil. On 09/10/2014 and 09/16/2014 you sold Lascadoil to a firm that manufactures animal feed.

SEE
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OF THIS
PAGE

EMPLOYEE(S) SIGNATURE

Jason D. Werne
Philip S. Woodward

EMPLOYEE(S) NAME AND TITLE (Print or Type)

Jason D. Werne, Investigator
Philip S. Woodward, Investigator

DATE ISSUED

11/19/2014

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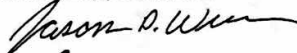

TYPE OF ESTABLISHMENT INSPECTED

Distributor

Amended FDA Form 483 – Previous FDA Form 483 collected from Adam Kremer on 09/18/2014. Amended FDA Form 483 issued to Adam Kremer on 9/19/2014.

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EMPLOYEE(S) NAME AND TITLE (*Print or Type*)

Jason D. Werne, Investigator
Philip S. Woodward, Investigator

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