

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

DISTRICT ADDRESS AND PHONE NUMBER 1201 Main Street, Suite 7200 Dallas, TX 75202 (214) 253-5200 Fax: (214) 253-5314	DATE(S) OF INSPECTION 12/31/2020-2/5/2021*
	FEI NUMBER 3006701521

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dylan R. Woods, Plant Manager

FIRM NAME Midwestern Pet Foods Chickasha Operation	STREET ADDRESS 913 N 9th St
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CITY, STATE, ZIP CODE, COUNTRY Chickasha, OK 73018-1817	TYPE ESTABLISHMENT INSPECTED Pet Food Manufacturer
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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 WE OBSERVED:

OBSERVATION 1

You did not identify and implement preventive controls to ensure that any hazards requiring a preventive control are significantly minimized or prevented.

Specifically,

A) You identified aflatoxin as a hazard requiring a preventive control in your manufacture of pet food containing corn and corn products. Your acceptance parameter for aflatoxin in corn and corn products at receiving is (b) (4). Your preventive controls failed to adequately control the hazard of aflatoxin in your firm's finished pet food products as evidenced by the following deficiencies:

1. Samples of your pet foods with lot code 03032205L38162, including SportMix Premium High Energy dog food and SportMix Original Recipe cat food, were collected from multiple sources in Missouri during the period 12/27/20 to 1/6/21 by Missouri Department of Agriculture. Total aflatoxin levels in these eight samples ranged from 483 ppb to 558 ppb. According to your records, this Lot code corresponds to the manufacturing/packaging date of (b) (4).
2. Samples of your pet foods were collected from multiple sources in Texas during the period 1/2/21 to 1/6/21 by the Office of the Texas State Chemist. Total aflatoxin in each of these seven samples was above your acceptable level, including Premium Energy Plus dog food with lot code 03032205L3B164 at 395 ppb, and SportMix Original Recipe cat food with lot code 04292205L3B163 at 125 ppb. According to

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Jennifer Owens Dowdy, Investigator Rendall E Barfoot, Investigator	Jennifer Owens Dowdy Investigator Signed By: Jennifer Owens Dowdy - 6 Date Signed: 02-05-2021 10:50:05 X	DATE ISSUED 2/5/2021

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your records, the lot codes of these seven samples correspond to manufacturing/packaging dates of (b) (4).

3. On 1/7/2021, the final analysis by your third-party laboratory of your retained samples of pet food products that contain up to (b) (4) % corn, manufactured/packaged on (b) (4) confirmed levels of aflatoxin greater than (b) (4) in your finished products, which were already distributed in interstate commerce:

Product Formula ID	Product Name	Date of Manufacture	Quantity Bagged (Lbs)	Total Aflatoxin
(b) (4)	SportMix Energy Plus 24/20	(b) (4)	(b) (4)	49.20 ppb
(b) (4)	SportMix Stamina 24/18	(b) (4)	(b) (4)	135.32 ppb
(b) (4)	SportMix High Energy 26/18	(b) (4)	(b) (4)	324.10 ppb
(b) (4)	SportMix Original Cat 30/10	(b) (4)	(b) (4)	428.04 ppb

4. On 1/8/2021, FDA collected samples of SportMix Premium High Energy dog food and SportMix Original Recipe cat food, Lot code 04292205, from retail store shelves in Chickasha, OK. Results of aflatoxin analysis were 27.2 ppb in the 31-lb bag of cat food and 21.5 ppb in the 15-lb bag of cat food. According

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to your records, these products were manufactured/bagged at your plant on (b) (4) .

- Your Preventive Control (b) (4) at receiving includes on-site sample collection and analysis for aflatoxin in incoming corn shipments but you did not implement your Preventive Control because you did not follow the protocol required to achieve results from the testing equipment you were using, both before 8/24/20 and after 8/25/20.

Your SOP for "Aflatoxin Testing" dated 8/17/18, states to "perform the testing according to (b) (4) (b) (4) instructions" and those instructions require the use of (b) (4) (b) (4) in the sample preparation; (b) (4) was used in sample preparation prior to 8/25/20.

Your SOP for "Aflatoxin Testing" (un-dated and in draft form but effective on 8/25/20 when the new test system was implemented), states to "perform testing according to (b) (4) instructions" and those instructions refer to the (b) (4) , which directs the use (b) (4) (b) (4) in the sample preparation; (b) (4) being used to properly prepare samples on/after 8/25/2020.

You have acknowledged that the (b) (4) was not being used prior to 8/25/20, and that the (b) (4) (b) (4) were not being used after 8/25/20, so samples of corn were not properly prepared to achieve accurate test results. Subsequently, your pet food products that contain corn were confirmed to have toxic levels of aflatoxin greater than (b) (4) .

- Your hazard analysis identifies Salmonella spp. as a hazard requiring a preventive control for ingredients received (b) (4)). The (b) (4) " is applied (b) (4) (i.e., after your preventive control identified to control Salmonella spp. in products). Your

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hazard analysis incorrectly identifies your (b) (4) program (i.e., (b) (4) (b) (4)) as the control for Salmonella spp. in the (b) (4) applied to the (b) (4) pet food. Your (b) (4) program does not control the hazard you identify in the (b) (4); therefore, you failed to implement a preventive control. As a result, you are not assuring that the Salmonella spp. is being significantly minimized or prevented and that the pet food manufactured at your facility is not adulterated.

OBSERVATION 2

You did not evaluate each known or reasonably foreseeable hazard for each type of animal food you manufacture, process, pack or hold in your facility.

Specifically,

Your hazard analysis does not identify or evaluate all reasonably foreseeable hazards in the raw materials you routinely receive, store, and use as ingredients in your extruded pet food products, including:

- A) Fumonisin, a hazard occurring in corn and corn products, which are ingredients in your pet food products.
- B) Vomitoxin (DON), a hazard that occurs in wheat midds and other grains such as corn, which are ingredients in your pet food products.

OBSERVATION 3

You did not conduct a reanalysis of your food safety plan as appropriate.

Specifically,

You have acknowledged that after implementing a different Aflatoxin testing system on 8/25/2020, you did not conduct a reanalysis of your Food Safety Plan to reflect the replacement of the old testing system or to reflect

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the addition of new equipment, or to include the required protocol to be followed for sample collections and preparation, instructions for conducting testing, equipment to be used, etc.

***DATES OF INSPECTION**

12/31/2020(Thu), 1/04/2021(Mon), 1/05/2021(Tue), 1/06/2021(Wed), 1/07/2021(Thu), 1/08/2021(Fri), 1/13/2021(Wed), 1/14/2021(Thu), 1/15/2021(Fri), 1/21/2021(Thu), 1/26/2021(Tue), 1/27/2021(Wed), 1/28/2021(Thu), 1/29/2021(Fri), 2/01/2021(Mon), 2/02/2021(Tue), 2/03/2021(Wed), 2/04/2021(Thu), 2/05/2021(Fri)

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