

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER
60 Eighth Street
Atlanta, GA 30309
404-253-1163

DATE(S) OF INSPECTION
12/21/2005 - 01/19/2006

FEI NUMBER

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Robert R. Petruzzi Plant Manager

FIRM NAME
Diamond Pet Food Processors of South Carolina, LLC

STREET ADDRESS
100 WoodTrail Drive

CITY, STATE AND ZIP CODE
Gaston, SC 29053

TYPE OF ESTABLISHMENT INSPECTED
Pet Food Manufacturer

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) ~~WAS~~ OBSERVED:

Item #1: Aflatoxin testing of finished pet food product retention samples of pet food manufactured between Sept 1, 2005 and Nov. 30, 2005 showed 16 batches of various pet food products with an Aflatoxin level 20 ppb or greater. Examples of aflatoxin test results in some of the product batches:

Batch Code	Manufacturing Date	Highest Aflatoxin Level in Retention Sample
DPA1001G	Oct 11, 2005	376 ppb
DMD1001J	Oct 11, 2005	280 ppb
DMD1001K	Oct 12, 2005	96 ppb
DMD1001F	Oct 4, 2005	75 ppb
DPA0901O	Oct 3, 2005	61 ppb

Item #2: Outside laboratory aflatoxin testing of four accepted incoming shipments of whole corn showed high levels of aflatoxin.

Weight Ticket	Date Received	Aflatoxin Level
G19519	Sept. 16, 2005	90 ppb
G20213	Oct. 10, 2005	1851 ppb
G20828	Oct. 31, 2005	111 ppb
G21488	Nov. 21, 2005	123 ppb

These whole corn shipments were used in the manufacturing of various pet food products.

SEE
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OF THIS
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EMPLOYEE(S) SIGNATURE

E. Harold Blackwood

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

E. Harold Blackwood Investigator

DATE ISSUED

01/19/2006

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

#3: Firm's written procedures require each shipment of incoming corn shipment be checked for aflatoxin. Records for the Aflatoxin testing of incoming whole corn did not always document that the tests were done or that the [REDACTED] test was performing properly.

A: Confirmatory aflatoxin testing on whole corn retention samples have found four incidences of false negative [REDACTED] tests and two false positive [REDACTED] tests. For example:

Weight Ticket	Date	[REDACTED] Result	2nd Test Result
G19519	09/16/05	Negative	90 ppb
G20213	10/10/05	Negative	1851 ppb
G20828	10/31/05	Negative	111 ppb
G21488	11/21/05	Negative	123 ppb
G19764	09/26/05	Positive	4 ppb
G19840	09/28/05	Positive	2 ppb

B: The Incoming Ingredient Inspection form did not list the results of the [REDACTED] test for approximately 12 of the [REDACTED] incoming whole shipments during September and October 2005.

C: On Dec. 7, 2005 only nine of [REDACTED] shipments of whole corn were tested for Aflatoxin.

D: There was no documentation of running a positive or negative control to ensure that the reagents of the [REDACTED] test were functioning properly.

#4: As per the firm's written procedures, retention samples of all bulk materials (including whole corn) are to be collected. Over 50% of the retention samples of incoming whole corn shipments from Sept. 1, 2005 to Nov. 30, 2005 are missing. Quality Control personnel who are responsible to ensure the collection and storage of retention samples failed to notice the retention samples were not being collected or were missing. Without the retention samples there can be no secondary check for Aflatoxin in those incoming corn shipments.

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TO: Robert R. Petruzzi Plant Manager

FIRM NAME Diamond Pet Food Processors of South Carolina, LLC	STREET ADDRESS 100 WoodTrail Drive
CITY, STATE AND ZIP CODE Gaston, SC 29053	TYPE OF ESTABLISHMENT INSPECTED Pet Food Manufacturer

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

#5: Accepted incoming bulk feed ingredients do not always meet the firm's ingredient specifications. Some of these ingredient specifications include ranges for protein, moisture, fat, ash, and fiber. The five listed specifications are checked by Near InfraRed Spectroscopy (NIR). Handwritten written results on the Receiving NIR Test Results Report for the time period 1/3/06 to 1/17/06 indicated that:

- A: 17 of 21 accepted shipments of wheat flour failed three or more of the five specifications tested by NIR.**
- B: All five accepted shipments of rice bran failed four out of five specifications tested by NIR.**
- C: Six of seven accepted shipments of Chicken By-Product Meal (Low Ash) failed all four specifications tested by NIR.**
- D: There was no documentation of NIR test results for whole corn for 2005.**

#6: Written procedures for receiving bulk materials do not reflect current practices. For example, verbal directions were made to disregard the black light testing of incoming corn shipments and test all corn shipments for aflatoxin. The form, Incoming Ingredient Inspection, for recording the inspection results of bulk material was changed at the first part of 2005.

#7: No acceptance criteria or testing conducted on fines stored outside in trailers.

#8: No BSE warning statement on invoice of pet food scrapes sold to local hog farmer.

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."