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發文日期:中華民國106年02月24日 發文字號:農牧字第1060042254號

速別:普通件

密等及解密條件或保密期限:

附件:如文(來函.pdf、FDA.pdf、food_safty_news.pdf)

主旨:有關美國Evanger's及Against the Grain牛肉口味犬隻 罐頭污染安樂死藥物Pentobarbital案,請查照。

說明:

- 一、依據駐美國代表處經濟組106年2月22日經美字第10600001 910號函辦理。
- 二、請轉知相關業者不得輸入、販售案內相關產品,倘業已輸 入,請參酌消費者保護法第36條:「直轄市或縣(市)政府 對於企業經營者提供之商品或服務,經第三十三條之調查 ,認為確有損害消費者生命、身體、健康或財產,或確有 損害之虞者,應命其限期改善、回收或銷燬,必要時並得 命企業經營者立即停止該商品之設計、生產、製造、加工 、輸入、經銷或服務之提供,或採取其他必要措施。」規 定辦理。
- 三、檢附函影本及附件1份供參。

正本:臺北市動物保護處、高雄市動物保護處、新北市政府動物保護防疫處、桃園市政 府動物保護防疫處、臺中市動物保護防疫處、臺南市動物防疫保護處、新竹縣家 畜疾病防治所、苗栗縣動物保護防疫所、彰化縣動物防疫所、南投縣家畜疾病防 治所、雲林縣動植物防疫所、嘉義縣家畜疾病防治所、嘉義市政府建設處、屏東







副本:本會畜牧處 2015-0224 交14-52:06章



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FDA Cautions Pet Owners and Caretakers Not to Feed Certain Evanger's or Against the Grain Canned Pet Foods Due to Adulteration with Pentobarbital

February 17, 2017

The U.S. Food and Drug Administration is advising pet owners and caretakers not to feed their pets <u>certain lots of Evanger's canned Hunk of Beef (/Safety/Recalls/ucm539900.htm)</u> or <u>Against the Grain Grain Free Pulled Beef with Gravy canned dog food (/Safety/Recalls/ucm541692.htm)</u> after unopened cans from both brands were found to contain pentobarbital, a barbiturate.

Pentobarbital is a drug that is used in animal euthanasia. It should not be in pet food and its presence as detected by the FDA in these products renders them adulterated.

The FDA was unable to determine from available records whether any other Evanger's or Against the Grain products made with beef contain any of the beef that went into the recalled products. Additionally, the agency concluded an inspection of the manufacturing facilities on February 14, 2017, and noted numerous significant concerns with conditions found at both the Wheeling.IL (/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM542050.pdf) and Markham.IL

(/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM542046.pdf) plants. These are initial observations and do not represent a final agency determination regarding the firm.

Following discussions with the FDA, Evanger's initiated a <u>voluntary recall (/Safety/Recalls/ucm539900.htm)</u> on February 3, 2017, of certain lots of its 12-ounce Hunk of Beef canned dog food: 1816E03HB, 1816E04HB, 1816E06HB, 1816E07HB, and 1816E13HB, all with an expiration date of June 2020.

In the course of the investigation, the FDA tested two cans of Against the Grain brand canned Grain Free Pulled Beef with Gravy dog food manufactured in the same facilities as Evanger's products and using beef from the same supplier: these samples also tested positive for pentobarbital. On February 9, 2017, after conversations with the FDA, Against the Grain **voluntarily recalled** (/Safety/Recalls/ucm541692.htm) lot 2415E01ATB12 BEST DEC 2019 of this product. The company issued a public notice about its recall on February 13, 2017. To date, the FDA is not aware of any pet illnesses associated with the Against the Grain product.

The FDA began investigating Evanger's Dog & Cat Food Company Inc. when it learned about five dogs in a single household that suffered acute neurological symptoms shortly after eating the product. One dog was euthanized after secondary complications, and three others recovered after receiving veterinary care. One of the dogs treated remains on seizure medication, and the fifth dog that ate the least amount of food recovered with time.

The stomach contents of the deceased dog and an open can of the product were tested by an FDA Veterinary Laboratory Investigation and Response Network lab, and unopened cans of the product from the pet owner and retailer that sold the products (from the same production lot), were tested by FDA's lab. All of the samples tested positive for pentobarbital.

In its recent press release announcing a limited product recall, Evanger's Dog & Cat Food Company, Inc. stated that the beef for its Hunk of Beef product came from a "USDA approved" supplier. However, the FDA reviewed a bill of lading from Evanger's supplier of "Inedible Hand Deboned Beef - For Pet Food Use Only. Not Fit For Human Consumption" and determined that the supplier's facility does not have a grant of inspection from the United States Department of Agriculture's Food Safety and Inspection Service. The meat products from this supplier do not bear the USDA inspection mark and would not be considered human grade. USDA-FSIS regulates slaughter of animals for human consumption only. Testing by USDA-FSIS of Evanger's Hunk of Beef confirmed that the meat used in the product was bovine (beef).

The investigation by the FDA is ongoing and includes examination of the suppliers of beef to Evanger's and Against the Grain to determine a possible cause for the presence of pentobarbital. The FDA is also coordinating with the USDA to address any possible areas of shared jurisdiction at the suppliers.

Oral exposure to pentobarbital can cause drowsiness, dizziness, excitement, loss of balance, nausea, nystagmus (eyes moving back and forth in a jerky manner), inability to stand, coma and death. Consumers who notice these symptoms in their pets should consult their veterinarian.

Consumers with cans of product subject to the facilities' voluntary recalls should refer to the firms' respective press releases for information about returning the product.

Additional Information

- How to Report a Pet Food Complaint (/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm182403.htm)
- Company Press Release: Evanger's Voluntarily Recalls Hunk of Beef Because Of Pentobarbital Exposure in one Batch of Food (/Safety/Recalls/ucm539900.htm)
- Company Press Release: Against The Grain Pet Food Voluntarily Recalls One Lot of Pulled Beef Due to Potential Adulteration with Pentobarbital (/Safety/Recalls/ucm541692.htm)
- FDA Form 483: Evanger's Dog (PDF 458KB)
 (/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM542050.pdf)
- FDA Form 483: Nutripack, LLC Markham, IL (PDF 575KB)
 (/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM542046.pdf)
- Veterinary Laboratory Investigation and Response Network (Vet-LIRN) (/AnimalVeterinary/ScienceResearch/ucm247334.htm)

Contact FDA

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Issued by: FDA, Center for Veterinary Medicine

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Food Safety News

Breaking news for everyone's consumption

Evanger's blames supplier, FDA, for Pentobarbital in dog food

FDA says beef suppliers are not registered; Evanger's hints at expanded recall By Phyllis Entis | February 22, 2017

Breaking news: Evanger's reveals presence of horse DNA in its Hunk of Beef dog food in a Wednesday letter to its customers. The company will recall all of its Hunk of Beef, Braised Beef Chunks with Gravy and Against the Grain Pulled Beef. The formal recall announcement will be issued this week.

Consumer complaints continue as the FDA digs deeper into operations at Evanger's pet food after discovering evidence that none of the company's meat suppliers are registered with USDA. Evanger's owners blamed their suppliers and the FDA in the wake of findings that their dog food contains a barbiturate used to euthanize animals.

At least one dog has died and at least four others required medical attention after eating Hunk of Beef canned dog food from Evanger's Dog & Cat Food Company Inc., which is owned by the Sher family. Evanger's and Nutripack LLC, another pet food company owned by members of the same family, have recalled certain lots of certain flavors of their canned dog food.

"The guilty party has turned out to be one of our most trusted meat suppliers. A USDA-APHIS inspected supplier who we had done business with for over 40 years, and whose plant we had visited numerous times over the years," said Evanger's owners Holly and Joel Sher in an online statement posted Sunday.

"We have taken it upon ourselves to lead the campaign to force the FDA to put an end to allowing drugs like pentobarbital to enter

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the raw material stream and contaminate our pets' food and endanger their lives."

Officials with the Food and Drug Administration do not agree with the company's contention that the agency is responsible for the pet food being contaminated.

"The detection of pentobarbital in pet food renders the product adulterated in violation of the Federal Food, Drug, and Cosmetic Act. Therefore, it is not acceptable to use animals euthanized with a chemical substance in pet or animal foods," an FDA spokesperson said Tuesday.

"It is the responsibility of the animal protein ingredient suppliers to implement practices at their facilities to ensure that euthanized animals are either not accepted at the facility, or to determine how they died and ensure euthanized animals are segregated from animal protein going for animal food use.

"Further, it is the responsibility of the pet food manufacturer to ensure that the food they produce is safe for consumption and properly labeled. One way that a manufacturer can do this is by taking steps to verify the identity and safety of the ingredients they receive from their suppliers."

During the course of their investigation, FDA inspectors discovered a bill of lading from Evanger's supplier, which listed "Inedible Hand Deboned Beef – For Pet Food Use Only. Not Fit For Human Consumption."

While FDA cannot reveal the identity of the supplier, an agency spokesperson described it as one that, "...provides materials from animals that are not fit for the human food supply, for a variety of reasons."

Evanger's sources the meat for its pet food from more than one supplier. According to the FDA spokesperson, the agency's "... preliminary assessment indicates that none of these suppliers are USDA-FSIS registered facilities."

Those findings are in direct contrast to statements from Evanger's and Nutripack LLC about their pet foods, which they say are made with human-grade food. FDA inspectors also found incomplete information on Evanger's brand and Nutripack's Against the Grain brand production records.

According to FDA, inspectors were unable to determine from company records whether any of the beef that was used in the recalled Evanger's and Against the Grain production lots was also used in any other products. In a letter to its customers released Feb. 21, Evanger's indicated the recall could be expanded to include all products containing chunk beef, "out of an abundance of caution."

The investigation so far

In a Friday consumer advisory, the FDA cautioned the public not to feed the recalled Evanger's and Against the Grain canned dog food products to their pets. The products in question were recalled on Feb. 3 and Feb. 9 by Evanger's Dog & Cat Food Company Inc. and Against the Grain, respectively, after pentobarbital was confirmed in samples of both products.

In conjunction with the advisory, FDA released two Inspectional Observation reports — Form 483 reports — which detailed the conditions found by the agency's inspectors during visits to Evanger's production facility in Wheeling, IL, and to the facility belonging to Nutripack LLC in Markham, IL.

The Wheeling operation had last been inspected by FDA in November 2012. According to a spokesperson with FDA, the Illinois Department of Agriculture performed an inspection in 2016 and classified the Wheeling facility as 'No Action Indicated.' However, the plant was not operating at the time, and the inspector was unable to observe the normal day-to-day activities. Nutripack had not been inspected either by the state or by the FDA prior to February 2017.

The USDA's Food Safety and Inspection Service (FSIS) is the federal agency tasked with oversight and inspection of slaughterhouses and meat processing operations. To be deemed "Fit for Human Consumption," any meat that enters interstate commerce must have been produced under USDA-FSIS supervision. Slaughterhouses and meat processing operations that do not engage in interstate commerce come under the supervision of the department of agriculture in their home state.

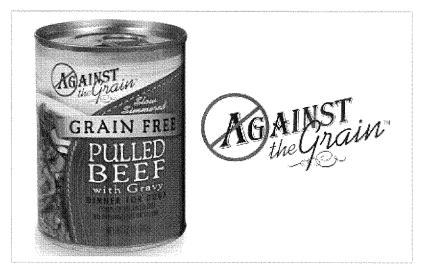
Evanger's is a private company, incorporated in Illinois. Its President and Agent of Record is Holly Sher, who owns the business together with her husband, Joel Sher.

Nutripack is a Limited Liability Company registered in Illinois. Its Agent of Record is Brett Sher, son of Joel and Holly Sher.

Nutripack is managed by Sher Services
Company Inc. Joel A. Sher is both the agent of record and the president of Sher Services, while Holly Sher is the secretary.

The Against the Grain trademark is registered to Chelsea Sher, daughter of Joel and Holly Sher. Chelsea Sher also is listed as Secretary of Evanger's.

In their online letter Sunday, the Sher family's reference to their supplier having been "USDA-APHIS inspected" suggests



they may not understand what agencies have jurisdiction over their pet food operations.

According to the USDA website the primary role of APHIS (Animal and Plant Health Inspection Service) in the U.S. food safety network of agencies "is to protect against plant and animal pests and diseases. APHIS also administers the Animal Welfare Act and carries out wildlife damage management activities."

On the other hand, according to USDA, the FSIS is "responsible for ensuring the safety and wholesomeness of meat, poultry, and processed egg products and ensures that it is accurately labeled."

As its investigation continues, FDA reports it has received additional complaints from consumers who fed Evanger's Hunk of Beef to their dogs, in some cases exclusively.

As consumers tend to throw out or recycle empty cans, obtaining specific lot number information has been difficult. The agency continues to encourage consumers to report problems with Evanger's products through the Safety Reporting Portal or by contacting a Consumer Complaint Coordinator. Additional information is available on the FDA web page, How to Report a Pet Food Complaint.

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發文日期:中華民國106年2月22日 發文字號:經美字第10600001910號

速別:最速件

密等及解密條件或保密期限:普通

附件:如文

主旨:有關美國Evanger's及Against the Grain牛肉口味狗罐頭污染安樂死藥物Pentobarbital事,詳如說明,請查參。

說明:

- 一、謹查,美國犬貓食品之主管機關為衛生部食品藥物管理署(FDA),依據該署網站公布資訊,Evanger's公司於本(106)年2月3日發布牛肉口味狗罐頭(Hunk of Beef Dog Food)回收資訊,原因為牛肉污染安樂死藥物Pentobarbital,已知有五隻狗因食用該罐頭而出現神經症狀,一隻已死亡。
- 二、FDA隨即啟動調查,經檢驗另一家公司Against the Grain之牛肉口味狗罐頭(Pulled Beef with Gravy),亦發現污染Pentobarbital;Against the Grain遂於本年2月14日發布產品回收資訊。FDA表示,前述兩家公司為同一家族企業,曾使用相同生產設施。雖然兩家公司皆聲稱肉品來源為食品等級,且經過美國農業部檢驗;但在查廠後,FDA發現肉品實為飼料等級。
- 三、FDA於本年2月17日發布通知(附件1),呼籲飼主不要餵飼寵物Evanger's及Against the Grain受到污染之牛肉口味狗罐頭,並說明實地檢查生產工廠後發現許多疑慮。事件發生後,面對各方關切寵物食品為何含有安樂死藥物、污染肉品如何進入食物鏈等連串問題,FDA回應認為寵物食品之安全及正確標示係生產者之責任,生產商應確保來源供應商提供產品之安全性。

四、另根據本年2月22日媒體報導(附件2), Evanger's牛肉口





味狗罐頭檢驗出馬肉成份。

正本:行政院農業委員會動植物防疫檢疫局、行政院農業委員會畜牧處

副本:經濟部國際貿易局、行政院農業委員會國際處 10010-02-2交 211:換52章

駐美國代表處經濟組



