

FDA RISK COMMUNICATION ADVISORY COMMITTEE
BRIEFING MATERIALS

2
3 **FDA LOGO**
4 FOR IMMEDIATE RELEASE
5

6 **Nationwide or Worldwide Urgent**
7 **[Product Type] Recall**

8 **Or**

9 **Nationwide or Worldwide Urgent**
10 **[Product Type] Correction**

11 **Or**

12 **Nationwide or Worldwide Urgent**
13 **[Product Type] Market Withdrawal**

14 *[Standard headline used to notify the press and general public about the seriousness and scope*
15 *of the problem. Descriptions of the distribution area, the affected product, and the action will*
16 *vary. Font: TNR-26b]*
17

18 **XXX Brand Product Xxx May Contain Xxx**
19 **Putting Consumers at Risk for Xxx**

20 *[Product specific sub-headline providing more detailed information about the problem and who*
21 *may be at risk. Font: TNR-22b]*
22

23 **What is the Problem and Who is at Risk? – XXX**

24 *[Company XXX is voluntarily [name the appropriate action—e.g., recalling, correcting usage*
25 *and/or patient monitoring directions, withdrawing from the market, etc.] product YYY. Describe*
26 *in general terms the scope of the affected products (e.g. single/multiple lots, sizes, varieties,*
27 *brands). Provide information about what is wrong with the product and how it may adversely*
28 *affect the public. Give specific information about groups most likely to be affected. If possible*
29 *provide useful information on the likely incidence of problem products and the denominator for*
30 *how many products are in use.*
31

32 *Include incidence and denominator data to help describe the magnitude of the risk, for example,*
33 *patients with implanted devices who may be alarmed by the news of a potential problem with*
34 *their device. Add other useful information which puts risk in perspective, for example, in the*
35 *case of ICDs or pacemakers... “This is a life-saving device. Malfunctions and failures are rare.*
36 *Even if the device fails to work properly, it usually will not harm the patient.”*
37

38 *Disclose, acknowledge, and explain any uncertainty about the cause of the problem and*
39 *potential outcomes. If no data is available, explain why*
40
41 *Explain what other specific circumstances put the patient at risk, for example, whether an*
42 *implant is more likely to fail within a specific period of time. Font: TNR-12]*
43

What Do [Consumers] [Patients] [Healthcare Providers] and Others Need To Do?

- XXX

[Provide information on what steps consumers, patients, and/or health care providers or others need to take to minimize risk from the problem – including information for consumers to seek medical advice from their physician as appropriate. Consumers, patients and others (health care providers, retailers, distributors, institutions, etc.) should be provided with information about what should be done with affected product. Use bullets as needed to distinguish items. Font: TNR-12]

44
45 **How to Identify the Product and Where is it Distributed? –XXX**
46 *[Provide information on how the public can easily identify the affected product including lot*
47 *numbers, company name and location, brand names, label identifiers, size, container shape,*
48 *dosage forms, links to digital photographs when available and appropriate, etc. Note any*
49 *ancillary materials that patients may have received that would identify the product, e.g., card for*
50 *implant, prescription label. Clearly identify the geographic area where the product is known or*
51 *believed to be distributed (e.g., a state, a series of states, nationwide, internationally, etc.) Font:*
52 *TNR-12]*

53
54 **What are the Symptoms of Illness/Injury? – XXX**
55 *[Provide basic information about the symptoms associated with the problem and how they can be*
56 *identified by consumers/patients and healthcare professionals. Special emphasis should be given*
57 *to describing the symptoms most indicative of severe injury or risk. If available, provide specific*
58 *information about actions consumers/patients should take if symptoms of serious illness occur,*
59 *e.g., “if you become dizzy, short of breath, etc. contact your doctor or emergency medical*
60 *personnel right away.” Font: TNR-12]*

61
62 **Other Important Information – XXX**
63 *[Additional information about the problem and what actions are being taken to resolve it.*
64 *Provide information about how distributors and customers are being notified. Provide*
65 *instructions on what distributors/retailers should do.]*

66
67 **Who Should be Contacted? – XXX**
68 *[Provide FDA (e.g. 1-888-SAFEFOOD) and/or company contact number(s), direct link to the*
69 *press release and any Dear Doctor or Dear Patient letters (not just the homepage) available on*
70 *the company’s website address(es) for consumers and other potentially affected parties to call*
71 *for information about the problem. Font: TNR-12]*

72
73 *[Provide information on how consumers can report any possible problem-related injuries to*
74 *FDA. In many cases, instructions are provided for filing MedWatch reports. In some situations,*
75 *consumers are advised to file complaints with consumer complaint coordinators in FDA district*
76 *offices. Font: TNR-12]*

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The information provided reflects FDA's best efforts to communicate information that has been reported to FDA. Its accuracy and comprehensiveness cannot be guaranteed (for FDA issued press). *[This statement affirms that FDA has knowledge of this situation.]*

What Do Consumers and Others Need To Do?

- Consumers should not consume these products, even if they appear to be normal, because of the potential serious risk to health.
- Consumers who have the affected products or who have used them in recipes should immediately throw the cans and food away.
- Products with no code or absence of a code that are subject to this recall should not be opened or used, and should be disposed of as described below.
- Consumers who are not sure if a product is subject to the recall should still throw it out as a precaution.
- Any food that may contain the recalled canned beans should be disposed of carefully. Skin contact should be avoided as much as possible, and hands should be washed immediately after handling the food.
- When disposing of these products, double-bag the cans in plastic bags. Make sure the bags are tightly closed, then place in a trash receptacle for non-recyclable trash outside of the home. Restaurants and institutions should ensure that such products are only placed in locked receptacles that are not accessible to the public. Additional instructions for safe disposal may be found at www.cdc.gov/ncidod/dbmd/diseaseinfo/botulism_g.htm.
- Individuals who have symptoms of botulism (described below) and who may have recently eaten the products under recall or other food products made with them should seek immediate medical attention.

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How to Identify the Product and Where is it Distributed?

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28 This recall involves all canned green beans and garbanzo beans distributed by New Era Canning
29 Company nationwide throughout the distribution chain including consumers' homes, nursing
30 homes, schools, warehouses, restaurants, retail stores, health care facilities, and other facilities
31 over the last five years.

32

33 The affected cans of green beans and garbanzo beans are large, institutional-sized containers,
34 weighing approximately six and a half pounds. New Era produces the canned green beans and
35 garbanzo beans under numerous brand names and labels. Therefore, the recalled products may
36 not necessarily be labeled with New Era's name.

37

38 The cans may bear a variety of codes beginning with "00249" or "GREEN" for green beans or
39 "00249" or "GARB" for garbanzo beans. It is also possible that the cans may not bear any codes
40 at all.

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42 For specific brands and codes of green beans and garbanzo beans that are subject to this recall,
43 consumers and retailers can access this information at the following link:

44 <http://www.fda.gov/oc/opacom/hottopics/newera.html>.

45

What are the Symptoms of Illness/Injury?

47 Symptoms of botulism poisoning in humans can begin from 6 hours to 2 weeks after eating food
48 that contains the toxin. Symptoms may include double vision, blurred vision, drooping eyelids,

49 slurred speech, difficulty swallowing, and muscle weakness that moves progressively down the
50 body, affecting the shoulders first, then descending to the upper arms, lower arms, thighs, and
51 calves. Botulism poisoning also can cause paralysis of the breathing muscles, which can result in
52 death unless assistance with breathing (mechanical ventilation) is provided.

53 **Other Important Information**

54 New Era Canning initiated this voluntary recall today in the interest of public health in
55 accordance with FDA's request to do so.

56 FDA and the Michigan Department of Agriculture launched a joint investigation of New Era's
57 processing plant. This investigation resulted in the identification of *C. botulinum* contamination
58 in several lots of canned green beans and one lot of garbanzo beans, the identification of serious
59 food violations, and this expanded recall. Original findings of this investigation resulted in the
60 company voluntarily recalling green beans in December 2007
61 (<http://www.fda.gov/bbs/topics/NEWS/2007/NEW01764.html>), and green beans, Mexican-style
62 chili beans, and dark red kidney beans in January, 2008
63 (http://www.fda.gov/oc/po/firmrecalls/newera01_08.html).

64 As part of the ongoing investigation, FDA issued an Order of Need for Emergency Permit to
65 New Era. This order prohibits the manufacture and shipment of the company's low acid canned
66 foods across state lines until they demonstrate to FDA's satisfaction that the products are safe. In
67 addition, the Michigan Department of Agriculture, under its state authority, has embargoed New
68 Era's entire inventory of low acid canned products contained in the company's warehouses in
69 Michigan. As a result, New Era is not currently distributing any products.

70 FDA initiated the inspection at New Era, along with inspections of other low acid canned food
71 (LACF) manufacturers, following four cases of botulism in consumers who had consumed
72 canned hot dog chili sauce in the summer of 2007. In light of these botulism cases, FDA
73 increased its inspection efforts to assure that manufacturers of all types of LACF products are
74 adhering to applicable FDA requirements. These actions illustrate the need for companies to
75 operate under adequate preventive control systems.

76 Prevention of foodborne illness is a key element of the FDA's new Food Protection Plan,
77 launched November 6, 2007.

78 **Who Should be Contacted?**

79
80 Customers with questions may contact New Era Canning at 1-800-282-9007 Ext. 111.
81 Additionally, anyone with questions may call FDA at 1-888-SAFEFOOD.
82

83 This recall is being made with the knowledge of the Food and Drug Administration. The
84 information provided reflects FDA's best efforts to communicate information that has been
85 reported to FDA. Its accuracy and comprehensiveness cannot be guaranteed.
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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

New Era Canning Company Announces New Nationwide Recall of Green Beans and Garbanzo Beans in #10 cans (6 to 7 pound cans)

Contact:

Linda Miller
1-800-282-9007 Ext 111

FOR IMMEDIATE RELEASE -- New Era, MI – January 18, 2008 --- New Era Canning Company of New Era, Michigan is recalling all cans of green beans and garbanzo beans in #10 cans (large cans containing between 6 and 7 pounds) because they may have been processed under conditions which could have led to contamination by *Clostridium botulinum* bacterium spores, which can cause life-threatening illness or death. The codes on the affected product begin with the numbers "00249," or the letters "GREEN" or "GARB". This recall does not include Italian Green Beans because that is a different product.

Clostridium botulinum bacterium spores have the potential for growth that produces a toxin that causes a potentially fatal form of food poisoning - botulism. Symptoms of botulism poisoning in humans can begin from 6 hours to 2 weeks after eating food that contains the toxin. Symptoms may include double vision, blurred vision, drooping eyelids, slurred speech, difficulty swallowing, and muscle weakness that moves progressively down the body, affecting the shoulders first, then descending to the upper arms, lower arms, thighs, and calves. Botulism poisoning also can cause paralysis of the breathing muscles, which can result in death unless assistance with breathing (mechanical ventilation) is provided. Individuals who have these symptoms and who may have recently eaten the green beans or garbanzo beans currently under recall or other food products made with these items should seek immediate medical attention.

The issues were uncovered in a FDA inspection of products that were in the company's possession. NO product has tested positive for the toxin and there have been NO cases of botulism reported from these products.

This recall only affects the products in the large #10 cans, the majority of which were potentially sold nationwide to various food service customers. However these products may also have been purchased by consumers at retail stores. The code on the cans may be embossed (stamped into the metal of the can) or printed in ink on one of the metal can ends.

Examples of how a code may appear on a can of green beans are: "00249 2BH7FL", "00249 1515 2BH7FL", "GREEN 2BH7FL" or "GREEN 1515 2BH7FL". (These are not necessarily actual can codes).

Examples of how a code may appear on a can of garbanzo beans are: "00249 34F7LG", "00249 1515 34F7LG", "GARB 34F7LG" or "GARB 1515 34F7LG". (These are not necessarily actual can codes).

New Era Canning, in conjunction with the US Food and Drug Administration and the Michigan Department of Agriculture, is thoroughly evaluating all processes and procedures to determine the cause of the problem.

Any food that may be contaminated should be disposed of carefully. Even tiny amounts of toxins ingested, inhaled, or absorbed through the eye or a break in the skin can cause serious illness. Skin contact should be avoided as much as possible, and the hands should be washed immediately after handling the food. Customers who have the product or any foods made with these products should throw them away immediately. Double bag the cans in plastic bags that are tightly closed, then place in a trash receptacle for non-recyclable trash outside of the home. Restaurants and institutions are encouraged to assure that such products are only placed in locked receptacles which are not accessible to the public. Additional instructions for safe disposal can be found at www.cdc.gov/botulism/botulism_faq.htm. Anyone with questions can call FDA at 1-888-SAFEFOOD.

Customers with questions may contact New Era Canning at 1-800-282-9007 Ext. 111.

The following product labels are affected:

Bunny brand, Distributed by Bunn Capitol Company, Springfield, IL

Blue Lake mixed and shortcut green beans (green beans, water, salt) in 6 lb. 5 oz. cans (UPC 6444500193).

Classic Sysco brand, Distributed by Sysco Corporation, Houston, TX.

Blue Lake cut green beans, 3 sieve (green beans, water, salt) in 101 oz. (6 lb. 5 oz.) cans (UPC 7486510779).

Blue Lake cut green beans, 4 sieve, (green beans, water, salt) in 101 oz. (6 lb. 5 oz.) cans (UPC 7486510487).

Garbanzo beans (garbanzo beans, water, salt, calcium chloride, EDTA) in 108.0 oz (6 lb. 12 oz.) cans (UPC 7486510484).

Code brand, Distributed by Code, Atlanta, GA.

Mixed & short cut green beans (green beans, water, salt) in 6 lb. 5 oz. cans (UPC 1207310120).

Fancy garbanzo beans without sulfites (garbanzo beans, water, salt, disodium EDTA) in 6 lb. 14 oz. cans (UPC 1207316120).

ComSource brand, Distributed by ComSource, Atlanta, GA.

Blue Lake cut green beans (green beans, water, salt) in 6 lb. 5 oz. cans (UPC 5254952333).

Blue Lake cut green beans, 3 sieve, (green beans, water, salt) in 6 lb. 5 oz. cans (UPC 5254952321).

ComSource Medallion Premium Quality brand, distributed by ComSource, Atlanta, GA.

Fancy Blue Lake cut green beans, 4 sieve, (green beans, water, salt) in 6 lb. 5 oz. cans (UPC 5254952325).

ComSource Merit Excellence Food Service brand, Distributed by ComSource, Inc, Atlanta, GA.

Cut Blue Lake green beans, 5 sieve (green beans, water, salt) in 6 lb. 5 oz. cans (UPC 5254952327).

Fancy Blue Lake cut green beans, 4 sieve, (green beans, water, salt) in 6 lb. 5 oz. cans (UPC 5254952325).

ComSource Traditional brand, Distributed by ComSource, Atlanta, GA.

Blue Lake cut green beans, mixed and short cut, (green beans, water, salt) in 101 oz (6 lb. 5 oz.) cans (UPC 5254952359).

Cut Blue Lake green beans, 4 sieve, (green beans, water, salt) in 6 lb. 5 oz. cans (UPC 5254952427).

Cut Blue Lake green beans, 5 sieve, (green beans, water, salt) in 6 lb. 5 oz. cans (UPC 5254952429).

Frosty Acres Restaurant's Pride Preferred brand, Packed for F.A.B., Inc., Alpharetta, GA.

Fancy Blue Lake cut green beans, 3 sieve (green beans, water, salt), in 101 oz. (6 lb. 5 oz.) cans (UPC 4820067373).

Cut Blue Lake green beans, 4 sieve (green beans, water, salt) in 101 oz. (6 lb. 5 oz.) cans (UPC 4820067445).

Blue Lake cut green beans, 5 sieve (green beans, water, salt) in 101 oz. (6 lb. 5 oz.) cans (UPC 4820067451).

Fancy cut Blue Lake green beans (green beans, water, salt), in 101 oz. (6 lb. 5 oz.) cans (UPC 4820067339).

Fancy cut Blue Lake green beans, 4 sieve (green beans, water, salt), in 101 oz. (6 lb. 5 oz.) cans (UPC 4820067446).

Mixture of Blue Lake short cut, cut green beans (green beans, water, salt), in 101 oz. (6 lb. 5 oz.) cans (UPC 4820068464).

Fancy garbanzos "chick pea" (garbanzo beans, water, salt, calcium chloride, disodium EDTA) in 111 oz. (6 lb. 15 oz.) cans (UPC 4820068264).

GFS brand, Distributed by Gordon Food Service, Grand Rapids, MI

Fancy Blue Lake cut green beans, 4 sieve (green beans, water, salt) in 6 lb. 5 oz. cans, reorder no. 118737 (UPC 9390111873).

Cut Blue Lake green beans, mixed sieve, (green beans, water, salt) in 6 lb. 5 oz. cans, reorder no. 273856 (UPC 9390127385).

goodtaste brand, Distributed by New Era Canning in New Era, MI.

Cut green beans (green beans, water, salt) in 6 lb. 5 oz. cans (UPC 3683512340).

Harvest Value brand, distributed by U.S. Food Service, Columbia, MD

Cut green beans, mixed and short cut, (green beans, water, salt) in 101 oz. (6 lb. 5 oz.) cans, 173619 (UPC 5810803534).

Cut green beans (green beans, water, salt) in 101 (6 lb. 5 oz.) cans, 170524 (UPC 5810801047).

Cut green beans, short cut (green beans, water, salt) in 101 oz. (6 lb. 5 oz.) cans, 173349 (UPC 5810803538).

Kitchen brand, Distributed by Potato Products, Detroit, MI.

5 sieve- EX.-STD. cut Blue Lake green beans (green beans, water, salt) in 6 lb. 6 oz. cans

Kitchen Essentials brand, Distributed by Gordon Food Service, Grand Rapids, MI.

Cut green beans, mixed sieve, (green beans, water, salt) in 6 lb. 6 oz. cans, reorder no. 156337 (UPC 9390115633).

Monarch brand, Distributed by Reid, Murdoch & Co., Columbia, MD

Extra Fancy Blue Lake cut green beans, 4 sieve, (green beans, water, salt) in 101 oz. (6 lb. 5 oz.) cans, 177039 (UPC 5810811196).

Fancy Blue Lake cut green beans, 3 sieve, (green beans, water, salt) in 101 oz (6 lb 5 oz) cans, 170672 (UPC 5810801040).

Monarch Premium brand, packed for PYA/Monarch, Inc, Greenville, SC.

Fancy Blue Lake cut green beans, 3 sieve, (green beans, water, salt) in 6 lb. 5 oz. cans, 173205 (No UPC code).

Mount Stirling brand, Distributed by Pocahontas Foods USA, Richmond, VA.

Blue Lake cut green beans, 5 sieve, (green beans, water, salt) in 6 lb. 5 oz. cans (UPC 4156033379).

Necco brand, Packed by New Era Canning Company, New Era, MI.

Cut green beans (green beans, water, salt) in 6 lb. 6 oz. cans (UPC 3683513340).

New Era brand, Distributed by New Era Canning Co, New Era, MI.

Veri-Green cut green beans (green beans, water, salt, zinc chloride) in 102 oz. (6 lb. 6 oz.) cans (No UPC code).

Cut green beans (green beans, water, salt) in 108 oz. (6 lb. 12 oz.) cans (UPC 3683511340).

Cut Blue Lake green beans, no salt added, (green beans, water) in 102 oz. (6 lb. 6 oz.) cans (No UPC code).

Garbanzo beans (garbanzo beans, water, salt, calcium chloride, EDTA) in 108 oz. (6 lb. 12 oz.) cans (UPC 3683511684).

Nugget brand, Distributed by Nugget, Atlanta, GA.

Green beans, 4 sieve, (green beans, water, salt) in 101 oz. (6lb. 5oz.) (UPC 4410540023).

Cut green beans, 5 sieve (green beans, water, salt) in 6 lb. 5 oz. cans (UPC 4410501930).
Veri-green cut green beans (green beans, water, salt, zinc chloride) in 6 lb. 12 oz. cans (UPC 4410502101).
Mixed short cut green beans (green beans, water, salt) in 6 lb. 5 oz. cans (UPC 4410518838).
Blue Lake cut green beans, 4 sieve, (green beans, water, salt) in 101 oz. (6 lb. 5 oz.) cans (UPC 4410501989).

Pocahontas brand, Distributed by Pocahontas Foods USA, Richmond, VA.

Fancy Blue Lake cut green beans, 4 sieve, (Blue Lake green beans, water, salt), 10282, in 6 lb. 5 oz. cans (UPC 4156010282).
Fancy long cut green beans (green beans, water, salt) in 6 lb. 5 oz. cans (UPC 4156010325).
Fancy Blue Lake green beans, 3 sieve, (Blue Lake green beans, water, salt), 10280, in 6 lb. 5 oz. cans (UPC 4156010280).

Reliance Sysco, Distributed by Sysco Corporation, Houston, TX.

Mixed cut green beans (green beans, water, salt) in 101 oz. (6 lb. 5 oz.) cans (UPC 7486512175).
Blue Lake cut green beans, 4 sieve, (green beans, water, salt) in 101 oz. (6 lb. 5 oz.) cans. (UPC 7486512172).
Blue Lake cut green beans, 5 sieve, (green beans, water, salt) in 101 oz. (6 lb. 5 oz.) cans (UPC 7486512174).

Sysco brand, Distributed by Sysco Corporation, Houston, TX.

5096342 Imperial Blue Lake cut green beans, 3 sieve (green beans, water, salt) in 6 lb. 5 oz. cans (UPC 7486512136).
5096359 Imperial Blue Lake cut green beans, 4 sieve (green beans, water, salt) in 6 lb. 5 oz. cans (UPC 7486512137).

US brand Distributed by U.S. FoodService, Columbia, MD.

Cut green beans, mixed sieve, (green beans, water, salt) in 101 oz. (6 lb. 5 oz.) cans, 171132 (UPC 5810801048).
Fancy Blue Lake cut green beans (green beans, water, salt) in 101 oz. (6 lb. 5 oz.) cans, 173416 (UPC 5810811195).
Fancy Blue Lake cut green beans, 3 sieve, (green beans, water, salt) in 101 oz. (6 lb. 5 oz.) cans, 170672 (UPC 5810801040).
Fancy Blue Lake cut green beans, 4 sieve, (green beans, water, salt) 170232 in 101 oz. (6 lb. 5 oz.) cans, 170672 (UPC 5810801041).
Cut green beans, 5 Sieve, (green beans, water, salt) in 101 oz (6 lb 5 oz) cans, 170675 (UPC 5810801042).

USDA, Food and Nutrition Service, Special Nutrition Programs, Alexandria, VA label.

Cut green beans (green beans, water, salt) in 6 lb. 6 oz. cans (UPC 1500101061).
Garbanzo beans (garbanzo beans, water, salt, calcium chloride, EDTA) in 6 lb. 12 oz. cans (UPC code 1500101089).

#

[New Era Canning Company \(Botulism\) Recall Page](#)

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33 This nationwide recall affects all lots of heparin and saline pre-filled flush syringes manufactured
 34 by AM2 PAT, Inc., of Angier, N.C. under the brand names Sierra Pre-filled, Inc. and B. Braun.
 35 They are sold in fill sizes of 3mL, 5mL and 10mL and syringe sizes of 6mL and 12mL.

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Sierra Pre-Filled Inc. Products:

NDC#	CATALOG #	Product
64054-1003-02	1003-02	Heparin Lock Flush 100units/mL 5mL
64054-1003-01	1003-01	Heparin Lock Flush 100units/mL 3mL
64054-3005-02	3005-02	Heparin Lock Flush 10units/mL 5mL
64054-3003-02	3003-02	Heparin Lock Flush 10units/mL 3mL
64054-3003-06	3003-06	Heparin Lock Flush 10units/mL 3mL (6mL syringe)
64054-3005-06	3005-06	Heparin Lock Flush 10units/mL 5mL (6mL syringe)
64054-0910-2	0910-12	Normal Saline IV Flush 10mL
64054-0905-2	0905-12	Normal Saline IV Flush 5mL
64054-0903-2	0903-12	Normal Saline IV Flush 3mL

39 **B. Braun Products:**

NDC#	CATALOG #	Product
64054-3005-02	513610	Heparin Lock Flush 10units/mL 5mL
64054-1003-01	513611	Heparin Lock Flush 100units/mL 3mL
64054-1003-02	513612	Heparin Lock Flush 100units/mL 5mL
64054-0903-2	513584	Normal Saline IV Flush 3mL
64054-0905-2	513586	Normal Saline IV Flush 5mL
64054-0910-2	513587	Normal Saline IV Flush 10mL

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What are the Symptoms of Illness/Injury?

Traditionally, *Serratia marcescens*, a bacterium found in water and soil has been linked to pneumonia, blood infections, and urinary tract and wound infections.

47 **Other Important Information**

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49 Some patients exposed to the recalled syringes have developed blood infections.

50

51 **Who Should be Contacted?**

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53 Consumers with questions may contact Sierra Pre-Filled at 919-552-9689, Monday through
54 Friday, 10 a.m. to 5 p.m. EST.

55

56 Any adverse reactions experienced with the use of the products, and/or quality problems should
57 also be reported to the FDA's MedWatch Program by phone at 800-FDA-1088, by fax at 800-
58 FDA-0178, by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, M.D. 20852-9787,
59 or on the MedWatch Web site at www.fda.gov/medwatch.

60

61 This recall is being made with the knowledge of the Food and Drug Administration. The
62 information provided reflects FDA's best efforts to communicate information that has been
63 reported to FDA. Its accuracy and comprehensiveness cannot be guaranteed.

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FOR EVALUATION USE ONLY



FDA News

FOR IMMEDIATE RELEASE

January 25, 2008

Media Inquiries:

Peper Long, 301-827-6242

Consumer Inquiries:

888-INFO-FDA

FDA Warns Public of Contaminated Syringes *AM2 PAT, Inc., issues nationwide recall of all pre-filled syringe flushes*

The U.S. Food and Drug Administration (FDA) today announced a nationwide recall of all lots of heparin and saline pre-filled flush syringes manufactured by AM2 PAT, Inc., of Angier, N.C. Two lots have been found to be contaminated with *Serratia marcescens*, a bacterium that can cause serious injury or death.

These syringes are manufactured by AM2 PAT under the brand names Sierra Pre-filled, Inc. and B. Braun. They are sold in fill sizes of 3mL, 5mL and 10mL and syringe sizes of 6mL and 12mL.

Consumers and health care facilities with any of the recalled, pre-filled Heparin Lock or Normal Saline IV Flush syringes should **stop using the product immediately**. Health care facilities should immediately quarantine the products in their inventory and return them to their distributor. Individual consumers should return them to the location from which they were received, such as a pharmacy or hospital. They should also let their health care providers know that they have been exposed to syringes recalled by FDA.

The recall affects all lots of these products. The FDA received information that Heparin Lock Flush syringes from Lot 070926H and Normal Saline IV syringes from Lot 070917A have been found to be contaminated with *Serratia marcescens*, and have resulted in patient infections. The U.S. Centers for Disease Control and Prevention has confirmed growth of *Serratia marcescens* from unopened heparin syringes.

Traditionally, *Serratia marcescens*, a bacterium found in water and soil has been linked to pneumonia, blood infections, and urinary tract and wound infections. Some patients exposed to the recalled syringes have developed blood infections.

The company voluntarily recalled these products on Jan. 18 after confirming bacterial contamination in some user samples.

Consumers with questions may contact Sierra Pre-Filled at 919-552-9689, Monday through Friday, 10 a.m. to 5 p.m. EST.

Any adverse reactions experienced with the use of the products, and/or quality problems should also be reported to the FDA's MedWatch Program by phone at 800-FDA-1088, by fax at 800-FDA-0178, by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, M.D. 20852-9787, or on the MedWatch Web site at www.fda.gov/medwatch.

MANUFACTURER: Sierra Pre-Filled, Inc., Angier, N.C.

PRODUCT DESCRIPTION:

Heparin Lock Flush Solution USP, All Strengths and Sizes

Normal Saline IV Flush Solution USP, All Strengths and Sizes

Sierra Pre-Filled Inc. Products:

NDC#	CATALOG #	Product
64054-1003-02	1003-02	Heparin Lock Flush 100units/mL 5mL
64054-1003-01	1003-01	Heparin Lock Flush 100units/mL 3mL
64054-3005-02	3005-02	Heparin Lock Flush 10units/mL 5mL
64054-3003-02	3003-02	Heparin Lock Flush 10units/mL 3mL
64054-3003-06	3003-06	Heparin Lock Flush 10units/mL 3mL (6mL syringe)
64054-3005-06	3005-06	Heparin Lock Flush 10units/mL 5mL (6mL syringe)
64054-0910-2	0910-12	Normal Saline IV Flush 10mL

64054-0905-2	0905-12	Normal Saline IV Flush 5mL
64054-0903-2	0903-12	Normal Saline IV Flush 3mL

B. Braun Products:

NDC#	CATALOG #	Product
64054-3005-02	513610	Heparin Lock Flush 10units/mL 5mL
64054-1003-01	513611	Heparin Lock Flush 100units/mL 3mL
64054-1003-02	513612	Heparin Lock Flush 100units/mL 5mL
64054-0903-2	513584	Normal Saline IV Flush 3mL
64054-0905-2	513586	Normal Saline IV Flush 5mL
64054-0910-2	513587	Normal Saline IV Flush 10mL

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[FDA Website Management Staff](#)

Contact: David Bogner
866-922-9222
September 18, 2007

FOR IMMEDIATE RELEASE

Nationwide Urgent Pet Food Recall

Bravo! Brand of Select Poultry Products May Be Contaminated with Salmonella and Listeria Monocytogenes Putting Consumers, Dogs and Cats at Risk

What is the Problem and Who is at Risk? – Bravo! announces a voluntary recall of select tubes of three of its poultry products for cats and dogs. The pet food is being recalled because two of the products have the potential to be contaminated with Salmonella and Listeria monocytogenes, while the other product has the potential to be contaminated with Listeria monocytogenes.

People may risk Salmonella infection not only by handling these pet foods, but also by contact with pets or other surfaces exposed to these foods, so it is important that they thoroughly wash their hands with hot water and soap.

This voluntary recall has been issued because the FDA detected the bacteria in samples during a recent review.

What Do Consumers and Others Need To Do?

- Anyone who is experiencing the symptoms of Salmonella or Listeria infection after having handled the recalled product should seek medical attention
- The recalled products should not be sold or fed to pets.
- Pet owners should return unopened frozen tubes of food to the store where purchased for a full refund.
- Pet owners should dispose of opened tubes of product in a safe manner (example, a securely covered trash receptacle) and return the washed plastic batch ID tag to the store where purchased for a full refund.
- In an effort to prevent the transmission of Salmonella from pets to family members and care givers, the FDA recommends that everyone follow appropriate pet food handling guidelines when feeding their pets. A list of safe pet food handling tips can be found at: http://www.fda.gov/cvm/CVM_Updates/foodbornetips.htm.
- People who have concerns about whether their pet has Salmonella or not should contact their veterinarian

*****PRESS RELEASE EXAMPLE*****
FOR EVALUATION USE ONLY

How to Identify the Product and Where is it Distributed? – The recalled products are distributed nationwide to distributors, retail stores, internet sales and directly to consumers, and they can be identified by the batch ID code located on the hang tag attached to the bottom of the plastic film tubes.

Product: Bravo Original Formula Chicken Blend frozen raw food

Product Numbers: 21-102, 21-105, 21-110

Sizes: 2 pound, 5 pound and 10 pound tubes

Batch ID code (on hang tag): 236

Reason for Recall: Salmonella, Listeria

Product: Bravo Original Formula Turkey Blend frozen raw food

Product Numbers: 31-102, 31-105, 31-110

Sizes: 2 pound, 5 pound and 10 pound tubes

Batch ID code (on hang tag): 236

Reason for Recall: Listeria

Product: Bravo Basic Formula Finely Ground Chicken frozen raw food

Product Number: 21-212

Size: 2 pound tube

Batch ID Code (on hang tag): 226

Reason for Recall: Salmonella, Listeria

Other Batch IDs for these same products are not involved in the recall.

What are the Symptoms of Illness/Injury? – Both Salmonella and Listeria are organisms which can cause serious infections in dogs and cats, and if there is cross contamination, in people, especially small children, frail or elderly people, and others with weakened immune systems. Healthy people with Salmonella infection may only suffer short-term symptoms, such as high fever, severe headache, vomiting, nausea, abdominal pain, and diarrhea. Long term complications can include arthritis and other more serious ailments. Healthy people with Listeria infection may only suffer short-term symptoms such as high fever, severe headache, stiffness, nausea, abdominal pain, and diarrhea. Listeria infection can cause miscarriages and stillbirths among pregnant women.

Other Important Information – The company has received no reports of illness in either people or animals associated with any of the three products. Healthy cats and dogs rarely become sick from Salmonella. Animals ill with Salmonella will display symptoms similar to the ones listed above for humans.

Who Should be Contacted? – Consumers may contact David Bogner at (866) 922-9222. For more information on the Bravo recall, please visit www.bravorawdiet.com.

Consumers may report any complaints to FDA's local District Complaint Coordinator's located on the FDA website: <http://www.fda.gov/opacom/backgrounders/complain.html>.

*****PRESS RELEASE EXAMPLE*****
FOR EVALUATION USE ONLY

This recall is being made with the knowledge of the Food and Drug Administration. The information provided reflects FDA's best efforts to communicate information that has been reported to FDA. Its accuracy and comprehensiveness cannot be guaranteed (for FDA issued press).

FOR EVALUATION USE ONLY



Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Bravo! Issues Nationwide Recall of Select Poultry Products for Dogs and Cats

Contact:

David Bogner
(866) 922-9222

FOR IMMEDIATE RELEASE --Vernon, CT -- Sept. 18, 2007--- Bravo! announces a voluntary recall of select tubes of three of its poultry products for cats and dogs. The pet food is being recalled because two of the products have the potential to be contaminated with Salmonella and Listeria monocytogenes, while the other product has the potential to be contaminated with Listeria monocytogenes.

Both Salmonella and Listeria are organisms which can cause serious infections in dogs and cats, and if there is cross contamination, in people, especially small children, frail or elderly people, and others with weakened immune systems. Healthy people with Salmonella infection may only suffer short-term symptoms, such as high fever, severe headache, vomiting, nausea, abdominal pain, and diarrhea. Long term complications can include arthritis and other more serious ailments. Healthy people with Listeria infection may only suffer short-term symptoms such as high fever, severe headache, stiffness, nausea, abdominal pain, and diarrhea. Listeria infection can cause miscarriages and stillbirths among pregnant women.

The company has received no reports of illness in either people or animals associated with any of the three products.

The recalled products are distributed nationwide to distributors, retail stores, internet sales and directly to consumers, and they can be identified by the batch ID code located on the hang tag attached to the bottom of the plastic film tubes. The recalled products should not be sold or fed to pets. Pet owners should return unopened frozen tubes of food to the store where purchased for a full refund. Pet owners should dispose of opened tubes of product in a safe manner (example, a securely covered trash receptacle) and return the washed plastic batch ID tag to the store where purchased for a full refund.

Recalled Pet Food

Product: Bravo Original Formula Chicken Blend frozen raw food

Product Numbers: 21-102, 21-105, 21-110

Sizes: 2 pound, 5 pound and 10 pound tubes

Batch ID code (on hang tag): 236

Reason for Recall: Salmonella, Listeria

Product: Bravo Original Formula Turkey Blend frozen raw food

Product Numbers: 31-102, 31-105, 31-110

Sizes: 2 pound, 5 pound and 10 pound tubes

Batch ID code (on hang tag): 236

Reason for Recall: Listeria

Product: Bravo Basic Formula Finely Ground Chicken frozen raw food

Product Number: 21-212

Size: 2 pound tube

Batch ID Code (on hang tag): 226

Reason for Recall: Salmonella, Listeria

Other Batch IDs for these same products are not involved in the recall.

Bravo! is issuing this action out of an abundance of caution and sincerely regrets any inconvenience to pet owners as a result of this announcement. This voluntary recall has been issued because the FDA detected the bacteria in samples during a recent review.

In an effort to prevent the transmission of Salmonella from pets to family members and care givers, the FDA recommends that everyone follow appropriate pet food handling guidelines when feeding their pets. A list of safe pet food handling tips can be found at:

http://www.fda.gov/cvm/CVM_Updates/foodbornetips.htm.

People may risk Salmonella infection not only by handling these pet foods, but also by contact with pets or other surfaces exposed to these foods, so it is important that they thoroughly wash their hands with hot water and soap. Anyone who is experiencing the symptoms of Salmonella or Listeria infection after having handled the recalled product should seek medical attention. Consumers may report any complaints to FDA's local District Complaint Coordinator's located on the FDA website: <http://www.fda.gov/opacom/backgrounders/complain.html>.

Healthy cats and dogs rarely become sick from Salmonella. Animals ill with Salmonella will display symptoms similar to the ones listed above for humans. People who have concerns about whether their pet has Salmonella or not should contact their veterinarian.

For more information on the Bravo recall, please visit www.bravorawdiet.com, or call toll free (866) 922-9222

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[FDA Website Management Staff](#)

Contact: Bodee LLC
(800) 935-0296
November 21, 2007

FOR IMMEDIATE RELEASE

Nationwide Urgent Drug Recall

Bodee LLC Brand Product of Encore Tabs May Contain Undeclared Ingredients Putting Consumers at Risk for Lowering Blood Pressure to Dangerous Levels

What is the Problem and Who is at Risk? – Bodee LLC is conducting this recall after being informed by representatives of the Food and Drug Administration (FDA) that lab analysis by FDA of Encore Tabs samples found the product contains potentially harmful, undeclared ingredients. FDA asserts that its chemical analysis revealed that one lot of Encore Tabs contains aminotadalafil, an analog of tadalafil, the active ingredient of a FDA-approved drug used for Erectile Dysfunction (ED). FDA maintains Aminotadalafil is close in structure to tadalafil and is expected to possess a similar pharmacological and adverse event profile. This undeclared chemical poses a threat to consumers because it may interact with nitrates found in some prescription drugs (such as nitroglycerin) and may lower blood pressure to dangerous levels.

Consumers with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates. ED is a common problem in men with these conditions, and consumers may seek these types of products to enhance sexual performance.

What Do Consumers and Others Need To Do?

- Customers who have this product in their possession should stop using it immediately
- Customers should contact their physician if they have experienced any problems that may be related to taking this product.

How to Identify the Product and Where is it Distributed? – Encore Tabs is sold in health food stores, via the internet and by mail order nationwide and in Canada. The Encore Tabs product is sold as a 2-capsule blister pack packaged in a retail booklet with five booklets in a box.

*****PRESS RELEASE EXAMPLE*****

FOR EVALUATION USE ONLY

What are the Symptoms of Illness/Injury? – This undeclared chemical poses a threat to consumers because it may interact with nitrates found in some prescription drugs (such as nitroglycerin) and may lower blood pressure to dangerous levels.

Who Should be Contacted? – The company advises that any unused portion be returned to Bodee LLC for a full purchase price refund by calling (800) 935-0296 for instructions on the return and refund process.

Any adverse events that may be related to the use of this product should be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088 or by fax at 1-800-FDA-0178 or by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787.

This recall is being made with the knowledge of the Food and Drug Administration. The information provided reflects FDA's best efforts to communicate information that has been reported to FDA. Its accuracy and comprehensiveness cannot be guaranteed (for FDA issued press).

FOR EVALUATION USE ONLY



Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Bodee LLC, Inc. Issues A Voluntary Nationwide Recall of All Encore Tabs, a Product Marketed as a Dietary Supplement

Contact:
Bodee LLC
(800) 935-0296

FOR IMMEDIATE RELEASE -- Century City, CA – November 21, 2007- Bodee LLC, 2222 Avenue of the Stars, 702E, Century City, CA 90067, announced today that it is conducting a voluntary nationwide recall of all the company's supplement product sold under the name Encore Tabs.

Bodee LLC is conducting this recall after being informed by representatives of the Food and Drug Administration (FDA) that lab analysis by FDA of Encore Tabs samples found the product contains potentially harmful, undeclared ingredients. FDA asserts that its chemical analysis revealed that one lot of Encore Tabs contains aminotadalafil, an analog of tadalafil, the active ingredient of a FDA-approved drug used for Erectile Dysfunction (ED). FDA maintains Aminotadalafil is close in structure to tadalafil and is expected to possess a similar pharmacological and adverse event profile. This undeclared chemical poses a threat to consumers because it may interact with nitrates found in some prescription drugs (such as nitroglycerin) and may lower blood pressure to dangerous levels.

Consumers with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates. ED is a common problem in men with these conditions, and consumers may seek these types of products to enhance sexual performance.

Encore Tabs is sold in health food stores, via the internet and by mail order nationwide and in Canada. The Encore Tabs product is sold as a 2-capsule blister pack packaged in a retail booklet with five booklets in a box.

Customers who have this product in their possession should stop using it immediately and contact their physician if they have experienced any problems that may be related to taking this product.

Any adverse events that may be related to the use of this product should be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088 or by fax at 1-800-FDA-0178 or by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787.

The company advises that any unused portion be returned to Bodee LLC for a full purchase price refund by calling (800) 935-0296 for instructions on the return and refund process.

The Company is taking this voluntary action because it is committed and is always concerned with the health of persons who have consumed this product. The Company is reviewing the procedures and policies of all firms involved with the manufacture of the product to ensure that there will be no future issues with regard to Encore Tabs' composition. The Company is working closely with the FDA in the recall process and is committed to the quality and integrity of its products. It sincerely regrets any inconvenience to consumers and its other customers.

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*****PRESS RELEASE EXAMPLE*****
FOR EVALUATION USE ONLY

FOR IMMEDIATE RELEASE

Contact: Sandy Walsh
301-827-6242
Consumer Inquiries:
888-INFO-FDA
March 29, 2007

Nationwide Urgent Drug Market Withdrawal

FDA Announces Voluntary Withdrawal of Pergolide Products - Agency Working with Product Manufacturers

What is the Problem and Who is at Risk? – The U.S. Food and Drug Administration (FDA) today announced that manufacturers of pergolide drug products, which are used to treat Parkinson's disease, will voluntarily remove these drugs from the market because of the risk of serious damage to patients' heart valves.

The products being withdrawn are Permax, the trade name for pergolide marketed by Valeant Pharmaceuticals, and two generic versions of pergolide manufactured by Par and Teva. Pergolide is in a class of medications called dopamine agonists and is used with levodopa and carbidopa to manage the symptoms (tremors and slowness of movement) of Parkinson's disease.

In 2006, an estimated 12,000 patients received prescriptions for pergolide from retail pharmacies in the United States.

There are alternative therapies available for Parkinson's disease, including three other dopamine agonists that have not been associated with valvular heart disease. The removal of pergolide products is not expected to adversely affect patient care because of the alternative therapies available.

FDA today is issuing a Public Health Advisory (PHA) detailing the removal of pergolide products from the market. The PHA, which is available at www.fda.gov/cder/drug/advisory/ pergolide.htm includes information and recommended actions for physicians, pharmacists and patients.

In light of this additional post-market safety information, the companies that manufacture and sell pergolide will stop shipping pergolide for distribution and, in cooperation with FDA, will withdraw the products from the market.

*****PRESS RELEASE EXAMPLE*****
FOR EVALUATION USE ONLY

What Do Patients and Others Need To Do?

- Patients taking pergolide should contact their doctors to discuss alternate treatments.
- Patients should not stop taking the medication, as stopping pergolide abruptly can be dangerous

What are the Symptoms of Illness/Injury? – Two recent New England Journal of Medicine studies confirm previous findings associating pergolide with increased chance of regurgitation (backflow of blood) of the mitral, tricuspid, and aortic valves of the heart. Valve regurgitation is a condition in which valves don't close tightly, allowing blood to flow backward across the valve. Symptoms include shortness of breath, fatigue and heart palpitations.

Other Important Information – Permax was approved in 1988 for Eli Lilly and Company as an adjunctive therapy with levodopa in Parkinson's disease. Valvular heart disease was first described in association with pergolide in 2002. In 2003, FDA asked Lilly to add valvulopathy (abnormality of cardiac valves) to the warnings section of Permax labeling, at which time a Dear Healthcare Practitioner letter was sent by Lilly. In 2006, the warning was upgraded to a black box warning, the FDA's strongest form of warning, because of new data concerning risks of heart valve damage.

The effect of the voluntary withdrawal on supplies of pergolide currently in pharmacies will not be immediate. This delay will allow time for health care providers and patients to discuss appropriate treatment options and time to change treatments.

FDA is working with the manufacturers of pergolide to determine if it might be possible, once the drug is withdrawn from the market, to make the drug available under an Investigational New Drug Application (IND) for those few patients who are currently receiving pergolide and who cannot be successfully converted to other available treatments.

This market withdrawal is being made with the knowledge of the Food and Drug Administration. The information provided reflects FDA's best efforts to communicate information that has been reported to FDA. Its accuracy and comprehensiveness cannot be guaranteed (for FDA issued press).



FDA News

FOR IMMEDIATE RELEASE

P07-54

March 29, 2007

Media Inquiries:

Sandy Walsh, 301-827-6242

Consumer Inquiries:

888-INFO-FDA

FDA Announces Voluntary Withdrawal of Pergolide Products

Agency Working with Product Manufacturers

The U.S. Food and Drug Administration (FDA) today announced that manufacturers of pergolide drug products, which are used to treat Parkinson's disease, will voluntarily remove these drugs from the market because of the risk of serious damage to patients' heart valves.

The products being withdrawn are Permax, the trade name for pergolide marketed by Valeant Pharmaceuticals, and two generic versions of pergolide manufactured by Par and Teva. Pergolide is in a class of medications called dopamine agonists and is used with levodopa and carbidopa to manage the symptoms (tremors and slowness of movement) of Parkinson's disease.

In 2006, an estimated 12,000 patients received prescriptions for pergolide from retail pharmacies in the United States. Patients taking pergolide should contact their doctors to discuss alternate treatments. Patients should not stop taking the medication, as stopping pergolide abruptly can be dangerous.

There are alternative therapies available for Parkinson's disease, including three other dopamine agonists that have not been associated with valvular heart disease. The removal of pergolide products is not expected to adversely affect patient care because of the alternative therapies available.

"Based on important new drug safety information, FDA has been working with the manufacturers of pergolide products to voluntarily remove these drugs from the market," said Douglas Throckmorton, M.D., deputy director of FDA's Center for Drug Evaluation and Research. "The FDA's increased evaluation of post-market safety is benefiting the public because, in this case, as new data about the product became available, we were able to remove a less safe drug from the market."

Two recent New England Journal of Medicine studies confirm previous findings associating pergolide with increased chance of regurgitation (backflow of blood) of the mitral, tricuspid, and aortic valves of the heart. Valve regurgitation is a condition in which valves don't close tightly, allowing blood to flow backward across the valve. Symptoms include shortness of breath, fatigue and heart palpitations.

In light of this additional post-market safety information, the companies that manufacture and sell pergolide will stop shipping pergolide for distribution and, in cooperation with FDA, will withdraw the products from the market.

Permax was approved in 1988 for Eli Lilly and Company as an adjunctive therapy with levodopa in Parkinson's disease. Valvular heart disease was first described in association with pergolide in 2002. In 2003, FDA asked Lilly to add valvulopathy (abnormality of cardiac valves) to the warnings section of Permax labeling, at which time a Dear Healthcare Practitioner letter was sent by Lilly. In 2006, the warning was upgraded to a black box warning, the FDA's strongest form of warning, because of new data concerning risks of heart valve damage.

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FDA is working with the manufacturers of pergolide to determine if it might be possible, once the drug is withdrawn from the market, to make the drug available under an Investigational New Drug Application (IND) for those few patients who are currently receiving pergolide and who cannot be successfully converted to other available treatments.

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Contact: Tama Antonia Donaldson
510-749-5449
August 31, 2007

FOR IMMEDIATE RELEASE

Worldwide Urgent Medical Device Correction

Abbott Notifies Users of Precision Xtra™, Optium™, ReliOn® Ultima, Rite Aid® and Kroger® Blood Glucose Meters to Check Display Screens

What is the Problem and Who is at Risk? – Abbott is initiating a worldwide medical device correction for users of its Precision Xtra™, Optium™, ReliOn® Ultima, Rite Aid® and Kroger® blood glucose meters manufactured after January 31, 2007. If the meter is dropped on a hard surface, part or all of the display screen may not work properly or may appear blank, which could result in an inability to view blood glucose test results. The inability to generate blood glucose results could result in significant risk for hypoglycemia or hyperglycemia.

Through internal testing, Abbott Diabetes Care has found that when recently produced meters are dropped onto a hard surface, part of the display can be jarred or disconnected, thereby making it difficult to read the lot number or date information, or causing the screen to appear blank.

Patients should keep their glucose meters in the wallet provided to offer additional protection for the meter. If the meter is dropped on a hard surface, patients should immediately perform a meter display check. Instructions on how to do this are detailed in the meter's Users Guide. If no problems are encountered during the automatic display check, the meter is ready for use.

What Do Consumers, Patients, Healthcare Providers and Others Need To Do?

- Users of these meters who note that the display screen is not working properly should immediately stop using their meter as referenced in the User Guide and call Abbott Diabetes Care customer care for assistance.

How to Identify the Product and Where is it Distributed? – Precision Xtra™, Optium, ReliOn® Ultima, Rite Aid® and Kroger® blood glucose meters manufactured after January 31,

*****PRESS RELEASE EXAMPLE*****

FOR EVALUATION USE ONLY

2007, and have been distributed via retail and mail order pharmacies, physician offices and distributors are subject to this notification.

Other Important Information – Blood glucose test strips used with these meters are not affected by this notification. Abbott is notifying physicians, pharmacists, distributors and registered users by letter.

No injuries have been reported to date.

Who Should be Contacted? – Customers may call Abbott Diabetes Care customer care at 1-877-844-4404 to determine the date their meter was manufactured. Customers may also call customer care if they have questions or need a replacement meter. More information about this notification is available on the company's website, www.abbottdiabetescare.com.

This correction is being made with the knowledge of the Food and Drug Administration. The information provided reflects FDA's best efforts to communicate information that has been reported to FDA. Its accuracy and comprehensiveness cannot be guaranteed (for FDA issued press).

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Urgent: Abbott Notifies Users of Precision Xtra™, Optium™, ReliOn® Ultima, Rite Aid® and Kroger® Blood Glucose Meters to Check Display Screens

Contact:

Tama Antonia Donaldson
(510) 749-5449

FOR IMMEDIATE RELEASE -- Alameda, CA -- August 31, 2007 -- Abbott is initiating a worldwide medical device correction for users of its Precision Xtra™, Optium™, ReliOn® Ultima, Rite Aid® and Kroger® blood glucose meters manufactured after January 31, 2007. If the meter is dropped on a hard surface, part or all of the display screen may not work properly or may appear blank, which could result in an inability to view blood glucose test results. The inability to generate blood glucose results could result in significant risk for hypoglycemia or hyperglycemia.

Users of these meters who note that the display screen is not working properly should immediately stop using their meter as referenced in the User Guide and call Abbott Diabetes Care customer care for assistance at 1-877-844-4404. Through internal testing, Abbott Diabetes Care has found that when recently produced meters are dropped onto a hard surface, part of the display can be jarred or disconnected, thereby making it difficult to read the lot number or date information, or causing the screen to appear blank. No injuries have been reported to date.

Patients should keep their glucose meters in the wallet provided to offer additional protection for the meter. If the meter is dropped on a hard surface, patients should immediately perform a meter display check. Instructions on how to do this are detailed in the meter's Users Guide. If no problems are encountered during the automatic display check, the meter is ready for use. Customers may call Abbott Diabetes Care customer care at 1-877-844-4404 to determine the date their meter was manufactured. Customers may also call customer care if they have questions or need a replacement meter.

Precision Xtra™, Optium, ReliOn® Ultima, Rite Aid® and Kroger® blood glucose meters have been distributed via retail and mail order pharmacies, physician offices and distributors. Abbott is notifying physicians, pharmacists, distributors and registered users by letter.

Blood glucose test strips used with these meters are not affected by this notification.

More information about this notification is available on the company's website, www.abbottdiabetescare.com.

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[FDA Website Management Staff](#)

Contact: Heidi Rebello
301-827-6242
May 2, 2007

FOR IMMEDIATE RELEASE

Nationwide Urgent Medical Device Recall

FDA Requests Recall of All Shelhigh Medical Devices

What is the Problem and Who is at Risk? – The U.S. Food and Drug Administration (FDA) today issued a formal written request to Shelhigh, Inc. to recall all of its medical devices remaining in the marketplace, including hospital inventories, because of sterility concerns. On [April 17, 2007](#), U.S. Marshals, at FDA's request, seized all medical devices including components at Shelhigh's Union, N.J. facility after finding significant deficiencies in the company's manufacturing processes. During the seizure, Shelhigh was asked to perform a voluntary recall of its products, but the company declined.

"Since these are critical devices implanted into seriously-ill patients, ensuring their sterility is absolutely essential to prevent infection," said Daniel Schultz, M.D., director, FDA's Center for Devices and Radiological Health. "FDA will continue to provide up-to-date information to patients and physicians about this ongoing public health matter."

The company's deficiencies, described in a [complaint](#) filed with the U.S. District Court of New Jersey, may compromise the safety and effectiveness of the devices. Shelhigh's own records indicate a number of sterility test failures and that its testing and retesting procedures were not properly performed.

Shelhigh devices are used in infants, children and adults.

What Do Consumers, Patients, Healthcare Providers and Others Need To Do?

- FDA recommends that doctors and hospitals consider using alternative products.

How to Identify the Product and Where is it Distributed? – The products include pediatric heart valves, tube-like devices for blood flow (conduits), surgical patches, dural patches to aid in tissue recovery after neurosurgery, annuloplasty rings to help repair heart valves, and arterial grafts. Physicians and patients concerned about Shelhigh devices can visit

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www.fda.gov/cdrh/safety/041907-shelhigh.html and
www.fda.gov/cdrh/medicaldevicesafety/atp/041907-shelhigh.html for more information,
including a list of the company's products.

Who Should be Contacted? – Adverse reactions or quality problems experienced with the use of these products may be reported to FDA's MedWatch Adverse Event Reporting program either online (www.fda.gov/medwatch/report.htm), fax (800-332-0178), or regular mail (use postage-paid FDA form 3500 available at: www.fda.gov/MedWatch/getforms.htm and mail to MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787).

FOR EVALUATION USE ONLY

Contact: Suanne Buggy or Lea Brooks
(916) 440-7259

FOR IMMEDIATE RELEASE

December 5, 2007

Nationwide Food Recall

California Department of Public Health Warns Consumers Not to Drink Metromint Flavored Water

What is the Problem and Who is at Risk? - Dr. Mark Horton, director of the California Department of Public Health (CDPH), today warned consumers not to drink Metromint brand flavored water because it may be contaminated with a bacterium called *Bacillus cereus*, a microorganism that may cause vomiting or diarrhea. Soma Beverage Co., LLC., of San Francisco is voluntarily recalling all bottles of Metromint brand flavored water (Peppermint, Spearmint, Orangemint and Lemonmint) with a "Best Before" date prior to 2008/12/21 (Dec. 21, 2008) and produced at its California facility because they may be contaminated with *Bacillus cereus*. The "Best Before" date is on the shoulder of the bottle.

What Do Consumers and Others Need To Do?

- Consumers in possession of the recalled product should discard it or return it to the point of purchase.
- Individuals who have become ill from drinking the product should contact their health care provider for evaluation.

How to Identify the Product and Where is it Distributed? – The products were packaged in clear plastic 16.9-ounce bottles with a black M on the front and the lettering "KSA" in a rectangle located on back of the bottle in the lower right-hand corner.

The product was distributed nationwide to grocery stores, including those in California, and sold on the Internet. The products were sold at the following locations in Northern California: Albertson's, Andronico's, Berkeley Bowl, BevMo!, Brown and Cole, Central Markets, Cost Plus World Market, Draeger's, Elephant Pharmacy, Fiesta Markets, Fred Meyer, Food Emporium, Haggen, Harmon's (UT), Lunardi's, Marlene's, Super Supplements, Mollie Stone's, New Seasons, PCC, Pharmaca, PW Markets, QFD, Rosauers, Safeway, Thriftway, Top Foods, Town and Country, Uwajimaya, Whole Foods Market, Wild Oaks Market, Yokes and Zupans. In Southern California, the products are sold at AJ's Fine Foods, Albertson's, Baron's Markets, BevMo!,

*****PRESS RELEASE EXAMPLE*****

FOR EVALUATION USE ONLY

Bristol Farms, Clark's Nutrition, Cost Plus World Market, Erewhon Market, Fry's, Gelson's, Henry's, Jensen's, Jimbo's Naturally, Lazy Acres, Mother's Market, New Frontiers, One World Fine Foods, Organic To Go, Pacific Coast Greens, Pavillions, Pharmaca, Ralph's, Sprouts, Sunflower, Vitality Juice and Java Bar, Vons, Wally's Win and Spirits, Wild Oats Market and Whole Foods Market.

What are the Symptoms of Illness/Injury? – Illness caused by *Bacillus cereus* may be either a vomiting or a diarrheal type. The vomiting type is characterized by nausea and vomiting within 30 minutes to six hours after consumption of contaminated foods. Duration of symptoms is generally less than 24 hours. The diarrheal type usually includes onset of abdominal cramps and watery diarrhea six to 15 hours after consumption of contaminated food. Symptoms may last for 24 to 48 hours.

Other Important Information – There have been no confirmed illnesses in California associated with this product to date. There is an illness complaint in Illinois that is possibly linked to consumption of this product.

Who Should be Contacted? – Consumers with questions may contact the company at (415) 979-0781, Ext. 101.

This recall is being made with the knowledge of the Food and Drug Administration. The information provided reflects FDA's best efforts to communicate information that has been reported to FDA. Its accuracy and comprehensiveness cannot be guaranteed (for FDA issued press).

FOR EVALUATION USE ONLY



FDA News

FOR IMMEDIATE RELEASEP07-78
May 2, 2007**Media Inquiries:**

Heidi Rebello, 301-827-6242

Consumer Inquiries:

888-INFO-FDA

FDA Requests Recall of All Shelhigh Medical Devices

The U.S. Food and Drug Administration (FDA) today issued a formal written request to Shelhigh, Inc. to recall all of its medical devices remaining in the marketplace, including hospital inventories, because of sterility concerns.

On [April 17, 2007](#), U.S. Marshals, at FDA's request, seized all medical devices including components at Shelhigh's Union, N.J. facility after finding significant deficiencies in the company's manufacturing processes. During the seizure, Shelhigh was asked to perform a voluntary recall of its products, but the company declined.

FDA recommends that doctors and hospitals consider using alternative products. Physicians and patients concerned about Shelhigh devices can visit www.fda.gov/cdrh/safety/041907-shelhigh.html and www.fda.gov/cdrh/medicaldevicesafety/atp/041907-shelhigh.html for more information, including a list of the company's products.

"Since these are critical devices implanted into seriously-ill patients, ensuring their sterility is absolutely essential to prevent infection," said Daniel Schultz, M.D., director, FDA's Center for Devices and Radiological Health. "FDA will continue to provide up-to-date information to patients and physicians about this ongoing public health matter."

The company's deficiencies, described in a [complaint](#) filed with the U.S. District Court of New Jersey, may compromise the safety and effectiveness of the devices. Shelhigh's own records indicate a number of sterility test failures and that its testing and retesting procedures were not properly performed.

Shelhigh devices are used in infants, children and adults. The products include pediatric heart valves, tube-like devices for blood flow (conduits), surgical patches, dural patches to aid in tissue recovery after neurosurgery, annuloplasty rings to help repair heart valves, and arterial grafts.

Adverse reactions or quality problems experienced with the use of these products may be reported to FDA's MedWatch Adverse Event Reporting program either online (www.fda.gov/medwatch/report.htm), fax (800-332-0178), or regular mail (use postage-paid FDA form 3500 available at: www.fda.gov/MedWatch/getforms.htm and mail to MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787).

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Recall -- State Press Release

California Department of Public Health Warns Consumers Not to Drink Metromint Flavored Water

Contact:

Suanne Buggy or Lea Brooks
(916) 440-7259

FOR IMMEDIATE RELEASE -- December 5, 2007 -- Dr. Mark Horton, director of the California Department of Public Health (CDPH), today warned consumers not to drink Metromint brand flavored water because it may be contaminated with a bacterium called *Bacillus cereus*, a microorganism that may cause vomiting or diarrhea. Soma Beverage Co., LLC., of San Francisco is voluntarily recalling all bottles of Metromint brand flavored water (Peppermint, Spearmint, Orangemint and Lemonmint) with a "Best Before" date prior to 2008/12/21 (Dec. 21, 2008) and produced at its California facility because they may be contaminated with *Bacillus cereus*. The "Best Before" date is on the shoulder of the bottle.

The product was distributed nationwide to grocery stores, including those in California, and sold on the Internet.

There have been no confirmed illnesses in California associated with this product to date. There is an illness complaint in Illinois that is possibly linked to consumption of this product.

The products were packaged in clear plastic 16.9-ounce bottles with a black M on the front and the lettering "KSA" in a rectangle located on back of the bottle in the lower right-hand corner.

The products were sold at the following locations in Northern California: Albertson's, Andronico's, Berkeley Bowl, BevMo!, Brown and Cole, Central Markets, Cost Plus World Market, Draeger's, Elephant Pharmacy, Fiesta Markets, Fred Meyer, Food Emporium, Haggen, Harmon's (UT), Lunardi's, Marlene's, Super Supplements, Mollie Stone's, New Seasons, PCC, Pharmaca, PW Markets, QFD, Rosauers, Safeway, Thriftway, Top Foods, Town and Country, Uwajimaya, Whole Foods Market, Wild Oaks Market, Yokes and Zupans.

In Southern California, the products are sold at AJ's Fine Foods, Albertson's, Baron's Markets, BevMo!, Bristol Farms, Clark's Nutrition, Cost Plus World Market, Erewhon Market, Fry's, Gelson's, Henry's, Jensen's, Jimbo's Naturally, Lazy Acres, Mother's Market, New Frontiers, One World Fine Foods, Organic To Go, Pacific Coast Greens, Pavillions, Pharmaca, Ralph's, Sprouts, Sunflower, Vitality Juice and Java Bar, Vons, Wally's Win and Spirits, Wild Oats Market and Whole Foods Market. Illness caused by *Bacillus cereus* may be either a vomiting or a diarrheal type. The vomiting type is characterized by nausea and vomiting within 30 minutes to six hours after consumption of contaminated foods. Duration of symptoms is generally less than 24 hours. The diarrheal type usually includes onset of abdominal cramps and watery diarrhea six to 15 hours after consumption of contaminated food. Symptoms may last for 24 to 48 hours.

Consumers in possession of the recalled product should discard it or return it to the point of purchase. Individuals who have become ill from drinking the product should contact their health care provider for evaluation.

Consumers with questions may contact the company at (415) 979-0781, Ext. 101.

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Cardinal Health Statement on Alaris Pump Module Worldwide Voluntary Recall

Contact:

Jim Mazzola
(614) 757-3690

FOR IMMEDIATE RELEASE --DUBLIN, OH -- December 20, 2007 --- Cardinal Health today issued the following update to the company's worldwide voluntary recall for its Alaris® Pump module:

On Nov. 5, 2007, Cardinal Health notified customers of a voluntary recall for all Alaris® Pump modules, model 8100 (formerly known as Medley™ Pump module), shipped prior to Sept. 27, 2007. Serial numbers for affected devices can be found at www.cardinalhealth.com/alaris/indexmodulealert.asp.

The reason for this recall is that the units may contain misassembled occluder springs (bent, broken, nested or missing). These conditions have occurred due to misassembly during manufacturing. Misassembled springs could lead to overinfusion that could result in serious adverse health consequences or death. Overinfusion may be difficult to detect because the misassembled springs can work intermittently, and there is no warning or notification of an overinfusion.

The company became aware of the issue from a review of customer complaints and service data. Cardinal Health has received one report of an injury and two reports of patient deaths associated with the use of this device. The deaths could not be confirmed by the respective hospitals or Cardinal Health as definitively caused by this issue.

Instructions to Customers

Any customer inquiries related to this action should be addressed to Cardinal Health's customer service center at 1-800-625-6627, with representatives available 24 hours a day, seven days a week. Additional information about the voluntary recall can also be found at www.cardinalhealth.com/alaris/indexmodulealert.asp.

Cardinal Health will work with customers to minimize disruption while completing an inspection of the devices as quickly as possible at the company's service facility and repairing those units with misassembled springs. This includes dispatching field teams to customer sites and using a loaner pool of temporary substitute Alaris pump modules with hospitals while their pumps are being inspected at Cardinal Health's facility. Any devices found with misassembled springs will be repaired and then returned to the customer, along with their other devices that have passed inspection.

In the interim, the company has developed an occluder pressure test to provide customers a method to potentially identify affected devices prior to Cardinal Health's inspection. The occluder pressure test may not be effective in detecting all misassembled occluder springs, and a further inspection by the company is required. This test method was posted as an updated service bulletin 528A at www.cardinalhealth.com/alaris/indexmodulealert.asp. Follow hospital protocol related to monitoring that your infusion pumps are functioning correctly during use.

Cardinal Health notified customers by registered letter, posted the customer letter on the Cardinal Health web site and set up a dedicated call center for customer support. The Food and Drug Administration (FDA) has also been apprised of this action. The voluntary recall covers Alaris® Pump modules that were distributed to 46 states, the District of Columbia, Canada, Guam, Puerto Rico and Saudi Arabia. There have been approximately 201,000 Alaris® Pump modules distributed worldwide that are affected by this recall. All units shipped after Sept. 27, 2007 have undergone a new inspection process to confirm correct assembly of the occluder springs, and therefore the company has not included these units as part of this recall. The company is working on product improvements to the pump to minimize the possibility for future misassembly of the springs.

Any adverse reactions experienced with the use of this product, and/or quality problems should also be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088, by Fax at 1-800-FDA-0178, by mail at MedWatch, HF-2, FDA 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch web site at www.fda.gov/medwatch.

About Cardinal Health

Headquartered in Dublin, Ohio, Cardinal Health, Inc. (NYSE: CAH) is an \$87 billion, global company serving the health-care industry with products and services that help hospitals, physician offices and pharmacies reduce costs, improve safety, productivity and profitability, and

deliver better care to patients. With a focus on making supply chains more efficient, reducing hospital-acquired infections and breaking the cycle of harmful medication errors, Cardinal Health develops market-leading technologies, including Alaris® IV pumps, Pyxis® automated dispensing systems, MedMined™ electronic infection surveillance service, VIASYS® respiratory care products and the CareFusion™ patient identification system. The company also manufactures medical and surgical products and is one of the largest distributors of pharmaceuticals and medical supplies worldwide. Ranked No. 19 on the Fortune 500 and No. 1 in its sector on Fortune's ranking of Most Admired firms, Cardinal Health employs more than 40,000 people on five continents. More information about the company may be found at www.cardinalhealth.com.

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Recall -- Firm Press Release

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MainStar America, LLC Issues Urgent Voluntary Nationwide Recall of Toothpaste

Contact:

Mr. Ernesto H. Botta
(305) 637-1127

FOR IMMEDIATE RELEASE -- Miami, FL -- June 13, 2007 -- MainStar America, LLC, Miami, Florida, is initiating a nationwide recall in accordance with the U.S. Food and Drug Administration (FDA) of the toothpaste made in China involving:

- Lot #20060708 – Item # 160-850 Dr. Cool Toothpaste 120 GR./4 OZ.
UPC # 6926597170008
- Lot #20060708 – Item # 160-852 Superdent Toothpaste 120 GR./4 OZ.
UPC # 6926597170015
- Lot #20060708 – Item # 160-860 Everfresh Smile2 Toothpaste 25 GR./ 1 OZ.
UPC # 6926597089539

This recall has been initiated because the products may contain the poisonous chemical diethylene glycol (DEG). DEG is used in antifreeze and as a solvent, and is a Central Nervous System depressant and potent kidney and liver toxin.

PLEASE RETURN ALL PRODUCTS IMMEDIATELY TO THE STORES WHICH YOU PURCHASED THEM.

CONSUMERS WHO HAVE THE PRODUCTS SHOULD STOP USING/ RETURN / THROW AWAY.

Retailers immediately examine your inventory and quarantine product subject to recall. In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification.

This voluntarily nationwide recall is being made with the knowledge of the U.S. Food and Drug Administration. **No injuries or illnesses have been reported to date in connection with this problem.**

Adverse Reactions or quality problems experience with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or fax.

Online: www.fda.gov/medwatch/report.htm

Regular Mail: use postage-paid FDA form 3500 available at www.fda.gov/MedWatch/getforms.htm

Mail to MedWatch 5600 Fishers Lane, Rockville, MD 20852-9787

Fax: 1-800-FDA-0178

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

The Hartz Mountain Corporation Recalls Vitamin Care for Cats Because of Possible Health Risk

Contact:

Ms. Denise Lenci
(516)241-6021

FOR IMMEDIATE RELEASE --Baconton, GA -- November 2, ,2007 ---The Hartz Mountain Corporation is voluntarily recalling one specific lot of Hartz Vitamin Care for Cats due to concerns that one or more bottles within the lot may have been potentially contaminated with *Salmonella*. Hartz is fully cooperating with the US Food and Drug Administration in this voluntary recall.

Salmonella is an organism which can cause serious infections in young children, frail or elderly people, and others with weakened immune systems, all of whom are at particular risk from exposure and should avoid handling these products.

Salmonella symptoms may include fever, diarrhea, abdominal pain, and nausea in both cats and humans. Anyone experiencing the symptoms of *Salmonella* infection should seek immediate medical attention. Owners of cats exhibiting these symptoms should also seek veterinary assistance.

The product involved is 3600 bottles of Hartz Vitamin Care for Cats, lot code SZ- 1637 1, UPC number 32700-97701, which was manufactured by a third party manufacturer, UFAC (USA), Inc., in Baconton, Georgia. While normal testing conducted by Hartz and UFAC has not revealed the presence of *Salmonella* in any Hartz products, sampling conducted by the FDA did detect the presence of *Salmonella*. Hartz is aggressively investigating the source of the problem.

Although the company has not received any reports of animals or humans becoming ill as a result of coming into contact with this product, Hartz is taking immediate steps to remove the product from all retail stores and distribution centers. Cat owners should check the lot code on their bottles, and, if the code is not visible, or if the bottle has lot code SZ- 16371 imprinted thereon, they should immediately discontinue use of the product and discard it in a proper manner.

Consumers can contact Hartz at 1-800-275-1414 with any questions they may have and to obtain reimbursement for purchased product.

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May 31, 2007: The Food and Drug Administration (FDA) is warning consumers in the West Chester, Pennsylvania area not to drink any "Jermuk" brand mineral water due to the risk of exposure to arsenic, a toxic substance and a known cause of cancer in humans. Jermuk Classic Medicinal Table Natural Sparkling Mineral Water in 0.5 liter green translucent glass bottles under the Jermuk Group brand label was recalled on 5/1/07 by AA Impex Group, Philadelphia, PA. Approximately, 200 bottles of the product were sold at the Great Pumpkin Corporation, 607 East Market Street, West Chester, PA, a retail store. FDA has sampled the product and found that it contains 536-539 micrograms of arsenic per liter of water. FDA's standard of quality for bottled water allows no more than 10 micrograms per liter. Product can be returned to the Great Pumpkin for a refund. There have been no illnesses reported at this time. Consumers who drank this water and have concerns are encouraged to contact their health care provider.

This release was revised on March 9, 2007. Revisions were made to the first paragraph.

FDA News

FOR IMMEDIATE RELEASE

P07-39

March 7, 2007

Media Inquiries:

Michael Herndon, 301-827-6242

Consumer Inquiries:

888-SAFEFOOD

FDA Warns Consumers Not to Drink "Jermuk" Brand Mineral Water Firms Recall Product

The Food and Drug Administration (FDA) is warning consumers not to drink certain brands of mineral water imported from Armenia due to the risk of exposure to arsenic, a toxic substance and known cause of cancer in humans. While arsenic is a well known human poison there is little chance that someone would become gravely ill if they consumed this product over a brief period of time (days to weeks). However, it is likely that they would experience nausea, abdominal pain and possibly vomiting which are clear indicators of arsenic toxicity, and therefore consumers should avoid ingestion of this bottled mineral water.

The products were distributed nationwide. The following products are being recalled:

- Zetlian Bakery, Inc., Pico Rivera, CA is recalling product with labels that read: "Jermuk Original Sparkling Natural Mineral Water Fortified With Natural Gas From The Spring". The product is additionally labeled as "2006 Jermuk Mayr Gortsaran CJSC" and "Imported by: Zetlian Bakery Inc."
- Importers Direct Wholesale Company Los Angeles, CA is recalling the product with labels that read: "Jermuk Sodium Calcium Bicarbonate and Sulphate Mineral Water". The product is additionally labeled as "Bottled by ARPI Plant, Republic of Armenia" and "Exclusive US importer and distributor: Importers Direct Wholesale Co., Los Angeles, CA".
- Kradjian Importing Company, Glendale, CA is recalling the product with labels that read: "Jermuk, Natural Mineral Water Sparkling". The product is additionally labeled as "Bottled by Jermuk Group CJSC" and "Sale Agent Kradjian Importing Co. Inc." in Glendale, CA

FDA sampled 500 milliliter (mL) green glass bottles and detected the problem. FDA is investigating whether other sizes or packaging are involved.

FDA testing of this water revealed 500 – 600 micrograms of arsenic per liter. FDA's standard of quality bottled water allows no more than 10 micrograms per liter.

There have been no illnesses reported at this time. Consumers who drank this water and have concerns are encouraged to contact their health care provider.

FDA will continue working to remove all such bottled water products from the marketplace. FDA may provide additional updates as more information becomes available.

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[Photos: Jermuk Brand Mineral Water](#)

[FDA's Pilot Program to Better Educate Consumers about Recalled Food Products](#)

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FDA News

FOR IMMEDIATE RELEASE

September 20, 2007

Media Inquiries:

Michael Herndon, 301-827-6242

Consumer Inquiries:

888-INFO-FDA

FDA Warns Consumers about the Risk of Cryptosporidium Illness from Baby's Bliss Gripe Water

The U.S. Food and Drug Administration (FDA) is warning consumers not to consume Baby's Bliss Gripe Water, apple flavor, with a code of 26952V and expiration date of October 2008 (shown as "10/08" on the label), distributed by MOM Enterprises, Inc., of San Rafael, Calif. FDA confirmed through laboratory analysis the presence of cryptosporidium after investigating the illness of a 6-week-old infant in Minnesota who consumed the product. Cryptosporidium is a parasite that can cause intestinal infections.

The most common symptom of infection is watery diarrhea. Other symptoms can include dehydration, weight loss, stomach cramps or pain, fever, nausea and vomiting. Symptoms generally begin two to ten days after becoming infected with the parasite and generally last one to two weeks. While most people with healthy immune systems will recover without treatment, the infection could be serious or life-threatening for certain individuals. Infants, children and pregnant women are susceptible to dehydration resulting from diarrhea, which can be life-threatening. Individuals with weakened immune systems are also at risk for a more serious and life-threatening form of illness.

Parents of children who have recently consumed Baby's Bliss Gripe Water, apple flavor, and have these symptoms should seek immediate medical attention. Parents and caregivers who have given this product to their infants and children should be alert for diarrhea and other signs of Cryptosporidium infection.

Approximately 17,600 bottles of the product were distributed nationwide in retail stores and sold over the Internet between November 2006 and September 2007. A code of 26952V with an expiration date of 10/08 appears on the bottle's carton. The product is sold in a four-ounce plastic bottle packaged inside of a cardboard carton which is labeled with the following: Baby's Bliss. Pediatrician Recommended Gripe Water. Apple Flavor. An herbal supplement used to ease the gas and stomach discomfort often associated with colic, hiccups, and teething. Dietary Supplement. 4 fl. ozs. (120 ml). Ginger Extract. Fennel Extract. Other ingredients: Deionized Water, Vegetable Glycerin, Fructose, Natural apple flavor, Citric acid, Bioflavonoid Extract, and Grapefruit Seed Extract. Distributed by: MOM Enterprises, Inc., San Rafael, CA 94903 USA. FDA advises consumers to throw away bottles of the product described above that they have in their possession.

MOM Enterprises, Inc. is fully cooperating with FDA's investigation into the cause of the contamination and is recalling all potentially contaminated products. FDA continues to investigate and will provide updates as more information becomes available. Consumers can call the FDA at 1-888-723-3366.

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FDA News

FOR IMMEDIATE RELEASE

P07-57

March 30, 2007

Media Inquiries:

Michael Herndon

Catherine McDermott

301-827-6242

Consumer Inquiries:

888-INFO-FDA

Company Recalls Single Product, Prescription Diet m/d Feline Dry Food

The Food and Drug Administration (FDA) today notified Hill's Pet Nutrition, Inc., of Topeka, Kansas, that FDA testing has detected melamine and melamine byproducts in wheat gluten received by the company to make dry cat food. FDA is conducting an investigation into pet food products made with wheat gluten that contains melamine and their association with reports of injury and deaths in cats and dogs.

Because the cat food is sold exclusively through veterinarians, Hill's has notified veterinarians, and is voluntarily recalling the pet food containing the wheat gluten and will conduct its own testing.

Consumers who have any bags of Prescription Diet m/d Feline should discontinue use. They should speak with their veterinarian if their pet shows any signs of kidney/renal illness. Such signs include loss of appetite, lethargy and vomiting.

"FDA recognizes that pets are very important to the American people and our sympathies go out to those who have lost their beloved pets," said Stephen Sundlof, D.V.M., director of the Center for Veterinary Medicine, Food and Drug Administration.

During two months in early 2007, Hill's Pet Nutrition manufactured Prescription Diet m/d Feline using wheat gluten from the same company that has supplied wheat gluten to Menu Foods, Inc. Menu Foods, Inc. (menufoods.com/recall) has also voluntarily recalled products potentially contaminated with melamine. See <http://www.fda.gov/oc/opacom/hottopics/petfood.html> for more information on the pet food recall.

The Hill's cat food now being recalled is labeled Prescription Diet m/d Feline dry food. The products are:

- 4 lb. bag, U.S. & Canada UPC code 52742 42770
- 10 lb. bag, U.S. & Canada UPC code 52742 42790

The agency is continuing to work with Menu Foods, Inc., and Hill's Pet Nutrition, Inc., to ensure the effectiveness of their recalls.

For more information, consumers may contact Hills Pet Nutrition at 1-800-445-5777 or visit www.HillsPet.com.

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FDA AMENDMENTS ACT OF 2007

SEC. 1003 - ENSURING EFFICIENT AND EFFECTIVE COMMUNICATIONS DURING A RECALL

The Secretary shall, during an ongoing recall of human or pet food regulated by the Secretary -

- (1) Work with companies, relevant professional associations, and other organizations to collect and aggregate information pertaining to the recall;

- (2) Use existing networks of communication, including electronic forms of information dissemination, to enhance the quality and speed of communication with the public; and

- (3) Post information regarding recalled human and pet foods on the Internet Web site of the Food and Drug Administration in a single location, which shall include a searchable database of recalled human foods and a searchable database of recalled pet foods that is easily accessed and understood by the public.