

Investigation of Acute Non-viral Hepatitis Illnesses – “Real Water” Brand Alkaline Water (March 2021)

FDA’s investigation is complete. CDC announces outbreak is over.

The FDA, along with the CDC and the Southern Nevada Health District, investigated a number of reports of acute non-viral hepatitis in the state of Nevada associated with “Real Water” brand alkaline water.

Real Water Inc. is not currently in operation. FDA collected consumer and non-consumer alkaline/non-alkaline water, chemicals, and concentrates. Laboratory analyses did not identify the contaminant that could have led to the illnesses. On June 1, 2021, FDA announced that Real Water Inc. has agreed to cease operations until they can comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act) and other requirements listed in a consent decree.

The FDA is reiterating that it is crucial that consumers, restaurants, distributors, and retailers not drink, cook with, sell, or serve “Real Water” alkaline water. FDA also advises that this water not be served to pets.

Recommendation

Although the firm is no longer in production, there may still be recalled products in consumers’ homes. Consumers, restaurants, distributors, and retailers should not drink, cook with, sell, or serve “Real Water” alkaline water, until more information is known about the cause of the illnesses. Further, FDA advises that this water not be served to pets. These products include but are not limited to: 5-gallon and 3-gallon containers (sold through home delivery/subscription), bottles of various sizes (sold on-line and in stores), and the “Real Water” concentrate (sold on-line).

The public is urged to report any product being offered for sale to the FDA Consumer Complaint Coordinator in their region.

According to the firm’s press release, the recalled alkaline water products are available nationwide, however the 5-gallon containers were distributed to the following areas: greater Las Vegas, NV area, central California coastal region (North of Los Angeles, CA, and South from Santa Barbara, CA), and Phoenix, AZ.

The firm’s press release also includes 1.5 liter, 1 liter, 500 ml and 1 gallon ready-to-drink alkaline water bottles and the 4 oz. concentrate.

Symptoms of all types of hepatitis, including non-viral hepatitis, are similar and can include fever, fatigue, loss of appetite, nausea, vomiting, abdominal pain, dark urine, clay or gray-colored bowel movements, joint pain, yellow eyes, and jaundice. Those experiencing these symptoms should contact their doctor.

Product Images







Case Counts

Total Illnesses: 21 Probable, 4 Suspect
Hospitalizations: 21 Probable, 2 Suspect
Deaths: 1

Last Illness Onset Date: 11/29/2020
States with Cases: CA (3 Probable), NV (18 Probable, 4 Suspect)

Previous Updates

June 1, 2021

On June 1, 2021, FDA announced that Real Water Inc. has agreed to cease operations until they can comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act) and other requirements listed in a consent decree. According to the complaint filed by the Department of Justice (DOJ) on behalf of the FDA, Real Water Inc. violated the FD&C Act by operating facilities that fail to meet preventive controls requirements to control food hazards. The complaint also alleges that defendants' products are adulterated within the meaning of the FD&C Act because they have been prepared, packed or held under insanitary conditions whereby they may have become contaminated with filth or may have been rendered injurious to health. More information can be found in the recently released press release and consent decree.

Outside of the cases considered as part of the consent decree, additional cases have been reported. On May 20, 2021, the Southern Nevada Health District is reporting five additional probable cases linked to its investigation of acute non-viral hepatitis illness in Clark County residents and the death of one person who was identified as a probable case. The patient who died was a woman in her 60s with underlying medical conditions and is one of the five new probable cases reported. This brings the total to 16 probable and one suspect case. Please note that these new cases are not included in the DOJ complaint.

The FDA is reiterating that it is crucial that consumers, restaurants, distributors, and retailers not drink, cook with, sell, or serve "Real Water" alkaline water. FDA also advises that this water not be served to pets.

Although the investigation is ongoing, current epidemiologic information indicates that this alkaline water product may be the cause of the illnesses.

April 26, 2021

On April 26, 2021 the Southern Nevada Health District announced, "The Health District has identified six additional probable cases (for a total of 11 probable cases) and one suspect case. The newly identified cases are all adults, and the one suspect case meets the clinical criteria but has not been tested for viral hepatitis."

The FDA has become aware that Real Water brand alkaline water is still being offered for sale through online retailers. The agency is working to locate any remaining products to ensure they are no longer available to consumers. The FDA will continue to monitor this situation closely and follow up with retailers as we become aware of recalled products being offered for sale.

Since the March 31 update, FDA investigators have completed inspections at the Real Water Inc. facilities in Henderson, NV and Mesa, AZ. FDA has also been provided some of the records requested. FDA is reviewing the information that has been provided by the firm, as well as reviewing the information that was collected during the inspections of the facilities. FDA is also sampling and analyzing Real Water products and will provide updates as the investigation continues.

The FDA is reiterating that it is crucial that consumers, restaurants, distributors, and retailers not drink, cook with, sell, or serve “Real Water” alkaline water. FDA also advises that this water not be served to pets.

Although the investigation is ongoing, current epidemiologic information indicates that this alkaline water product may be the cause of the illnesses.

As this outbreak investigation continues, the FDA will provide additional updates to this advisory as more information becomes available.

March 31, 2021

The FDA has become aware that “Real Water” brand alkaline water is still being offered for sale through online retailers. The agency is working to locate any remaining products to ensure they are no longer available to consumers. The FDA will continue to monitor this situation closely and follow up with retailers as we become aware of recalled products being offered for sale.

In addition, the FDA is conducting an audit to gauge the effectiveness of the voluntary recall initiated by Real Water, Inc. As of March 31, 2021, the audit has found that, prior to contact by FDA, a number of distributors had not received notification directly from the firm about the recall. Additionally, as of March 31 2021, Real Water Inc. is still promoting the product via social media despite issuing a recall announcement.

Therefore, the FDA is reiterating that it is crucial that consumers, restaurants, distributors, and retailers not drink, cook with, sell, or serve “Real Water” alkaline water.

Given a lack of cooperation by the firm, FDA investigators have been unable to complete investigations at the Real Water, Inc. facilities in Henderson, NV, and Mesa, AZ, and have not been provided with requested records. As a result, on March 23 and on March 25, FDA issued a Demand for Records under section 414 of the Federal Food, Drug, and Cosmetic Act.

March 26, 2021

On March 25, 2021, in addition to the information reported in the firm’s recall, FDA learned that that 3- and 5-gallon containers of Real Water brand drinking water were distributed in the state of Utah.

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Consumption of “Real Water” brand alkaline water is the only common link identified among all of these cases to date. This brand of alkaline water is owned by Real Water Inc., headquartered in Mesa, Arizona.

Although the investigation is ongoing, current epidemiologic information indicates that this alkaline water product may be the cause of the illnesses.

As this outbreak investigation continues, the FDA will provide additional updates to this advisory as more information becomes available.

March 25, 2021

On March 24, 2021, Real Water, Inc. of Mesa, AZ, and Henderson, NV, issued a recall of all sizes of its Real Water brand drinking water and concentrate.

According to the firm's press release, the recalled alkaline water products are available nationwide, however the 5-gallon containers were distributed to the following areas: greater Las Vegas, NV area, central California coastal region (North of Los Angeles, CA and South from Santa Barbara, CA), and Phoenix, AZ.

The firm's press release also includes 1.5 liter, 1 liter, 500 ml and 1 gallon ready-to-drink alkaline water bottles and the 4 oz. concentrate.

As this outbreak investigation continues, the FDA will provide additional updates to this advisory as more information becomes available.

March 24, 2021

Given a lack of cooperation by the firm, FDA investigators have been unable to complete investigations at the "Real Water" Inc. facilities in Henderson, NV and Mesa, AZ and have not been provided with any records. As a result, on March 23, FDA issued a Demand for Records under section 414 of the Federal Food, Drug, and Cosmetic Act.

Consumption of "Real Water" brand alkaline water is the only common link identified among all of these cases to date. This brand of alkaline water is owned by Real Water Inc., headquartered in Mesa, Arizona.

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As this outbreak investigation continues, the FDA will provide additional updates to this advisory as more information becomes available.

On March 19, 2021, the firm's website reported that the 5-gallon containers are delivered to homes in several areas of the country through distributors. Since then, the firm has removed this information from the website, but has not provided any information about this to the FDA. The FDA investigation has determined that at least one distributor, in the Honolulu, Hawaii, area and one distributor in Orange County, CA no longer has a partnership with Real Water Inc.

The other areas that the firm had reported receiving 5-gallon containers were:

- St. George, UT through Real Water Southern Utah
- Tucson, AZ through Aqua Pure
- Ventura and Santa Barbara, CA through Real Water Gold Coast

Real Water, Inc. has not provided FDA the records requested regarding distribution, therefore, FDA cannot conclusively determine if the above firms did or did not distribute Real Water. These records are included in FDA's Demand for Records.

Additionally, according to the firm's website, Real Water is sold in 1 gallon, 500 mL (16.9oz.), 1 liter, and 1.5 liter plastic bottles and in a 750 mL glass bottle.

March 19, 2021

The consumption of “Real Water” brand alkaline water is the only common link identified among all of these cases to date. This brand of alkaline water is owned by Real Water Inc., headquartered in Mesa, Arizona.

Although the investigation is ongoing, epidemiologic information currently indicates that this alkaline water product may be the cause of the illnesses.

FDA is in the beginning stages of this investigation, and there may be additional products connected to this outbreak. FDA has initiated an investigation at the firm.

As this outbreak investigation continues, the FDA will provide additional updates to this advisory as more information becomes available.

March 16, 2021

On March 13, the FDA was alerted to five cases of acute non-viral hepatitis (resulting in acute liver failure) in infants and children that occurred in November 2020 with an unknown cause reported to the Southern Nevada Health District. All five patients had been hospitalized but have since recovered. All patients were reported to have consumed “Real Water” brand alkaline water. These patients came from four different households. Five additional people, two adults and three children, from two of the four households were reported to have experienced other symptoms as well. Less severe symptoms included fever, vomiting, nausea, loss of appetite, and fatigue.

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