

PENNSYLVANIA DEPARTMENT OF HEALTH
2018 - PAHAN – 410 – 05-11- UPD
Update: *Burkholderia cepacia*
complex Infections Associated with
Use of Medline Remedy® Essentials
No-Rinse Foam



DATE:	05/11/2018
TO:	Health Alert Network
FROM:	Rachel Levine, MD, Secretary of Health
SUBJECT:	UPDATE: <i>Burkholderia cepacia</i> complex Infections Associated with Use of Medline Remedy® Essentials No-Rinse Foam
DISTRIBUTION:	Statewide
LOCATION:	Statewide
STREET ADDRESS:	Statewide
COUNTY:	Statewide
MUNICIPALITY:	Statewide
ZIP CODE:	Statewide

This transmission is a “Health Update” that provides updated information regarding an incident or situation; no immediate action necessary.

HOSPITALS: PLEASE SHARE WITH ALL MEDICAL, PEDIATRIC, INFECTION CONTROL, NURSING, AND LABORATORY STAFF IN YOUR HOSPITAL

EMS COUNCILS: PLEASE DISTRIBUTE AS APPROPRIATE

FQHCs: PLEASE DISTRIBUTE AS APPROPRIATE

LOCAL HEALTH JURISDICTIONS: PLEASE DISTRIBUTE AS APPROPRIATE

PROFESSIONAL ORGANIZATIONS: PLEASE DISTRIBUTE TO YOUR MEMBERSHIP

LONG-TERM CARE FACILITIES: PLEASE SHARE WITH ALL MEDICAL, INFECTION CONTROL, AND NURSING STAFF IN YOUR FACILITY

- UPDATE:**
- DOH continues to work with the CDC, FDA and other state and local health departments to investigate an outbreak of *Burkholderia cepacia* complex (Bcc) infections associated with Medline Remedy® Essentials No-Rinse Foam.
 - **DOH and FDA are advising health professionals and consumers to avoid using all lots of Medline Remedy Essentials No-Rinse Cleansing Foam, manufactured by Shadow Holdings dba Bocchi Laboratories, as these products might be contaminated with several species of *Burkholderia cepacia* complex (Bcc).**
 - The FDA is investigating whether other products manufactured by Shadow Holdings dba Bocchi Laboratories may be contaminated with Bcc and may present a risk to consumers.
 - Remain alert for additional notices related to this investigation.

DOH is recommending all Pennsylvania healthcare facilities and consumers avoid using all lots of Medline Remedy Essentials No-Rinse Cleansing Foam, manufactured by Shadow Holdings dba Bocchi Laboratories.

As described in 2018-PAHAN-405-04/17, DOH requests that healthcare facilities that have used this product since November 2017 conduct a retrospective review of microbiology laboratory records for *Bcc* infections among non-cystic fibrosis patients occurring **on or after 1/1/2018**.

DOH requests that healthcare facilities and/or local health departments notify DOH Bureau of Epidemiology immediately about similar clusters of *Bcc* among non-cystic fibrosis patients occurring **on or after 1/1/2018** by contacting their local health department or by calling 1-877- PA-HEALTH.

A portion of the FDA notification issued on May 8, 2018 relating to this *Bcc* outbreak is included below. To read the entire notification, please access <https://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm607082.htm>.

Fast Facts

- The FDA is advising health professionals and consumers to avoid using all lots of Medline Remedy Essentials No-Rinse Cleansing Foam, manufactured by Shadow Holdings dba Bocchi Laboratories at this time, as these products might be contaminated with several species within the bacteria *Burkholderia cepacia* complex (*Bcc*).
- Shadow Holdings dba Bocchi Laboratories has recalled certain lots of the product.
- The FDA is investigating whether other products manufactured by Shadow Holdings dba Bocchi Laboratories may be contaminated with *Bcc* and may present a risk to consumers.
- As of May 7, 2018, CDC reports that there are 10 confirmed cases of *Bcc* associated with use of Medline Remedy Essentials No-Rinse Cleansing Foam (seven in Pennsylvania, one in New Jersey and two in California). These patients were already hospitalized for acute conditions and acquired the infections while hospitalized.
- This cleansing foam is a product used for skin and perineal care. It is used in hospitals and home-health care settings for people who are unable to shower or bathe after surgery or due to other acute health conditions. FDA is particularly concerned about contamination in this product, since product instructions do not include rinsing the product from patient skin. This poses a risk to persons who might be immunocompromised or have other underlying medical conditions.
- State and federal health officials have collected samples of the product from multiple locations, including affected hospitals. As of May 7, 2018, there have been multiple product samples that tested positive for *Bcc*. Isolates from these product samples match clinical strains isolated from case patients by Pulsed Field Gel Electrophoresis (PFGE). Additionally, an environmental swab collected at Shadow Holdings, dba Bocchi Laboratories during FDA's investigation has tested positive for a strain of *Bcc*. Given these positive samples, the FDA is advising the public to not use any Medline Remedy Essentials No-Rinse Cleansing Foam products at this time.
- The FDA will update the public with more information as it becomes available.

What is the Problem and What is being Done About It?

CDC reports that there are 10 confirmed cases of infection caused by bacteria within the *Burkholderia cepacia* complex, also commonly called *B. cepacia*, in three states: California (2), Pennsylvania (7), and New Jersey (1). These patients were already hospitalized for acute conditions and acquired the infections while hospitalized. The infections have been linked to the Medline product, Remedy Essentials No-Rinse Cleansing Foam.

On March 28, 2018, Shadow Holdings dba Bocchi Laboratories of Santa Clarita, CA, announced a voluntary recall of 4oz and 8oz bottles of Medline Remedy Essentials No-Rinse Cleansing Foam lots that had been identified as positive for *B. cepacia*, including lot numbers: M05703, M06691, and M07247. The FDA is currently investigating this matter further to determine whether any additional products or lots may present a risk to consumers.

Because FDA's investigation is ongoing, the FDA is advising health professionals and consumers to avoid using all lots of Medline Remedy Essentials No-Rinse Cleansing Foam at this time, as this product may be contaminated with *B. cepacia* and there is a potential for severe patient infection. Samples of the product that were collected by FDA from a hospital and distribution center tested positive for *B. cepacia*; isolates from these samples match clinical isolates collected from ill persons by Pulsed Field Gel Electrophoresis (PFGE), a type of DNA fingerprinting. Additionally, an environmental swab collected at Shadow Holdings, dba Bocchi Laboratories during FDA's investigation has tested positive for a strain of *B. cepacia*. The FDA is currently investigating this matter further to determine whether any additional products or lots may present a risk to consumers.

Health care professionals and patients should discard all recalled lots of Remedy Essentials No-Rinse Cleansing Foam. As the investigation continues, additional lots and additional products might be identified as potentially harmful. In the interim, facilities should avoid using all other lots of this product, particularly in patients at greater risk for *B. cepacia* infection, until further information is available.

Any hospital or company that purchased Medline Remedy Essentials No-Rinse Cleansing Foam should immediately quarantine material under their control and contact Shadow Holdings dba Bocchi Laboratories. Patients, pharmacies, hospitals, and home health care facilities should immediately stop using and dispensing Medline Remedy Essentials No-Rinse Cleansing Foam.

FDA will continue to work with CDC and state and local health departments in affected states to gather additional information.

Categories of Health Alert messages:

Health Alert: conveys the highest level of importance; warrants immediate action or attention.

Health Advisory: provides important information for a specific incident or situation; may not require immediate action.

Health Update: provides updated information regarding an incident or situation; unlikely to require immediate action.

This information is current as of May 11, 2018, but may be modified in the future. We will continue to post updated information regarding the most common questions about this subject.