

PENNSYLVANIA DEPARTMENT OF HEALTH
2018 - PAHAN – 413 – 06-06- UPD
Update: *Burkholderia cepacia*
complex Infections Associated with
Use of Medline Remedy® Essentials
No-Rinse Foam



DATE:	06/06/2018
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 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 recalled lots (including M05703, M06691, M07247, and M07476) of Medline Remedy Essentials No-Rinse Cleansing Foam, manufactured by Shadow Holdings dba Bocchi Laboratories, as these products might be contaminated with Burkholderia cepacia complex (Bcc).**
- **DOH and FDA are advising health professionals and consumers to avoid using additional recently recalled products (see below), manufactured by Shadow Holdings dba Bocchi Laboratories, due to potential contamination with Burkholderia cepacia complex (Bcc).**
- The FDA is investigating whether these other products manufactured by Shadow Holdings dba Bocchi Laboratories may also be contaminated with Bcc and may present a risk to consumers.
- Remain alert for additional notices related to this investigation.

Shadow Holdings dba Bocchi Laboratories has issued a voluntary recall expanding the recall initially issued on March 28, 2018 to include:

1. An additional master lot of the Medline Remedy® Essentials No-Rinse Foam. The expanded recall includes lot **M07476** in addition to previous recalled lots M05703, M06691, and M07247.
2. Medline Remedy® Essentials No-Rinse Foam 4-ounce bottles from the M05703 master lot. The initial recall only included 8 oz. bottles from this lot.
3. Personal care products regulated by FDA as cosmetics.
4. Over-the-counter topical pain relief gel and shave/acne creams regulated by FDA as medications.

DOH and FDA are advising health professionals and consumers to avoid using all recalled products, manufactured by Shadow Holdings dba Bocchi Laboratories, due to potential contamination with *Burkholderia cepacia* complex (Bcc).

For a complete list of the personal care products and lot numbers that have been recalled by Shadow Holdings (including the lots of the Medline Remedy® Essentials No-Rinse Foam) follow the below instructions:

1. Go to <https://www.accessdata.fda.gov/scripts/ires/index.cfm>
2. Click on the Advanced Search tab
3. Type “Shadow Holdings” into the Recalling Firm and click Search

For a list of all recalled over-the-counter products (regulated as Medications by FDA) go to <https://www.fda.gov/Safety/Recalls/ucm609003.htm>

DOH is recommending all Pennsylvania healthcare facilities and consumers to avoid using products that have been recalled by Shadow Holdings dba Bocchi Laboratories, as these products may be contaminated with the bacteria *Burkholderia cepacia* complex (Bcc). The FDA is particularly concerned about potential contamination in recalled lots of Medline Remedy Essentials No-Rinse Cleansing Foam, since FDA testing has found and matched Bcc from product samples to environmental samples collected from the Shadow Holdings dba Bocchi Laboratories facility and from ill persons. For more information, please refer to FDA’s update: <https://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm607082.htm>.

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 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.

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 June 6, 2018, but may be modified in the future. We will continue to post updated information regarding the most common questions about this subject.