GOJO

HAND HYGIENE TIMES

Your resource for the latest news in effective infection control program development and best practices.

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Newly-Released FDA Tentative Final Monograph: What Does it Mean for My Healthcare Facility?

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On April 30, 2015, the Food and Drug Administration (FDA) issued a proposed rule requesting additional scientific data to support the safety and effectiveness of certain active ingredients used in health care antiseptics marketed under the over-the-counter drug monograph.

What is an over-the-counter (OTC) drug monograph?

OTC drug monographs are a practical alternative to the FDA reviewing individual drugs on the market, as is the process with prescription drugs. The monograph is a "recipe book" that specifies allowed ingredients, doses, and formulations and provides a set of labeling and testing requirements for manufacturers. There are three phases of the public rulemaking process that establishes a monograph.

Phase 1: an FDA-appointed advisory review panel comprised of scientifically qualified experts evaluate data about the ingredients and classify them into three different categories:

- *Category I:* Generally recognized as safe and effective (GRASE)
- *Category II:* Not GRASE – these active ingredients cannot be marketed and sold
- *Category III:* Not enough data to make a final decision on safety and effectiveness, but sufficient data for the sale of products containing these active ingredients until the monograph is finalized.

Phase 2: the FDA evaluates information, including panel findings, public comments, and additional data that had become available and was eligible for inclusion. After this evaluation process, the agency publishes its tentative conclusions as proposed rules in the *Federal Register*. These are referred to as tentative final monographs (TFM). Once a TFM is published, manufacturers can develop and market products that comply with TFM requirements.

Phase 3: the FDA considers the comments and responses to the published TFM and new data received. Then, FDA publishes a final rule (called a final monograph) that establishes standards for both the active ingredients and the labeling in each OTC drug category. Upon publication of a final monograph, only active ingredients that are GRASE are included. Category I-III designations are no longer used and the final monograph is followed. This document is first published in the *Federal Register*, and later in the Code of Federal Regulations.

How does the proposed ruling on April 30, 2015 affect clinical practices within my healthcare facility?

Within the new proposed rule, the FDA is establishing a new, protocol-driven safety framework to ensure that hand hygiene products used by healthcare workers are both safe and effective. This framework did not exist in the previous OTC monograph; therefore, all antiseptic ingredients' statuses were changed and by default have been moved to a Category IIISE (designation for safety and effectiveness). In the announced proposed rule, the FDA was clear that this does not mean there was a safety signal of any sort alerting the FDA to a potential problem with efficacy or safety. It means that since the FDA began review of health care antiseptics in the 1970s, many things have changed, including the frequency of use of some of these products, hospital infection control practices, new technology that can detect low levels of antiseptics in the body, the FDA's safety standards, and scientific knowledge about the impact of widespread antiseptic use. As a result of these changes, the FDA is simply asking for more data.

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THAT'S a FACT!

The final rule, or final monograph for healthcare antiseptics is scheduled to be published in January 2018 and will be a part of the Code of Federal Regulations.

Refer to the April 30, 2015 FDA News Release for more information.

Product Feature

PROVON® SUPPORTS YOUR HIGH QUALITY CARE

NEW- PROVON Ultra Mild Foam Handwash

Our Best Mild Soap Ever[1]

As a leader in skin health and hand hygiene GOJO understands that effective formulations are important in sustaining your hand hygiene and skin care regimen. As part of a total solution GOJO offers the PROVON line of hand soaps with a full range of antimicrobial and non-antimicrobial solutions that help reduce the spread of germs that can cause infection while being gentle to the skin.

This PROVON Ultra Mild Foam Handwash gentle formula is as mild as baby wash, and it helps maintain skin health even after repeated washing.[2] It is formulated with a blend of moisturizers that maintain the skin's natural moisture barrier, yet still rinse away quickly, leaving your hands feeling clean and refreshed. The formulation has a light, clean fresh scent that dissipates quickly, providing a positive scent experience that does not interfere with your daily work. Product has been awarded USDA BioPreferred® designation.

Choose the PROVON line of products from GOJO, the leading brand in antibacterial skin care solutions and make PROVON an integral part of your regimen for maintaining good hygiene, reducing odors and infections, preventing skin breakdown and promoting good skin health.

Description	Order Number	Case Pack	Uses Dispenser
PROVON Antimicrobial Handwash Products			
PROVON Antibacterial Foam Handwash			
LTX™ 1200 mL Refill	1942-02	2	1971-04
LTX 700 mL Refill	1342-03	3	1371-04
ADX™ 1250 mL Refill	8822-03	3	8871-06
ADX 700 mL Refill	8722-04	4	8771-06
PROVON Foaming Antimicrobial Handwash with PCMX			
LTX 1200 ml Refill	1944-02	2	1971-04
ADX 1250 ml Refill	8825-03	3	8871-06
PROVON Non-Antimicrobial Handwash Products			
PROVON Clear & Mild Foam Handwash			
LTX 1200 mL Refill	1941-02	2	1971-04
LTX 700 mL Refill	1341-03	3	1371-04
ADX 1250 mL Refill	8821-03	3	8871-06
ADX 700 mL Refill	8721-04	4	8771-06
PROVON Green Certified Foam Hand Cleaner			
TFX™ 1200 mL Refill	5382-02	2	2745-12
FMX™ 1250 mL Refill	5182-03	3	5160-06
PROVON Ultra Mild Foam Handwash			
LTX 1200 mL Refill	1943-02	0	1971-04
LTX 700 mL Refill	1343-03	3	1371-04
ADX 1250 mL Refill	8833-03	3	8871-06

1. When compared to other PROVON formulations.
2. GOJO Industries, Inc. clinical evaluation study 2014-02-110361, 2/2014

Should I stop using alcohol-based hand rubs (ABHR) or other healthcare antiseptics as a result of the proposed rule?

No. The FDA itself has stated that product use should continue in compliance with well-established standards of care in health care settings as additional data are gathered. Antiseptic products, especially ABHR, are mission-critical for preventing healthcare-associated infections and transmission of microorganisms. The Association of Professionals in Infection Control (APIC) and the Society for Healthcare Epidemiology of America (SHEA) emphasize that healthcare antiseptics are an important component of infection control strategies in healthcare settings and remain a standard of care to prevent illness and spread of infection. The proposed rule does not require any health care antiseptic products that are compliant with the TFM be removed from the market at this time. Instead, it requires manufacturers to supply additional information to the FDA. Once the monograph is finalized, ingredients for which adequate safety and effectiveness data have been provided will continue to be available.

Refer to the April 30, 2015 FDA News Release for more information.

A Look Ahead

next month's issue