Medical News

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FDA Issues Tentative Final Monograph for First Aid Antiseptic Drug Products

The Food and Drug Administration (FDA) issued its proposed changes for over-the-counter (OTC) first aid antiseptics. The proposal, 21 CFR Parts 33 and 369, was published in the July 22, 1991 *Federal Register.* Some of the changes are listed below.

The FDA proposed that skin wound cleansers and skin wound protectants containing active antimicrobial ingredients be deleted as separate drug product categories and be included in a new category identified as "first aid antiseptics." The category "skin antiseptic" would be deleted as a separate category and be included in "first aid antiseptics." In addition, products previously listed as skin wound protectants, skin wound cleansers, and skin antiseptics would be identified as "first aid antiseptics."

The phrase "First aid to help" would be followed by: "prevent;" "decrease" ("the risk of' or "the chance of'); "reduce" ("the risk of' or "the chance of'); "guard against" ("infection," "bacterial contamination," or "skin infection"); or "protect against" ("infection," "bacterial contamination," or "skin infection"). This sentence ("First aid to help, etc.") would be completed with the phrase "in minor cuts, scrapes, and burns." This change, according to the FDA, is to provide consistent labeling for first aid antiseptics and first aid antibiotics.

The definition for first aid antiseptics would be "An antiseptic-containing drug product applied topically to the skin to help prevent infection in minor cuts, scrapes, and burns."

Skin wound cleansers and skin wound protectants without active antimicrobial ingredients would not fall within the scope of the antimicrobial rulemaking.

Iodine (tincture and solution) and phenol (0.5% to 1.5%), formerly placed in Category III as skin wound cleansers, skin wound protectants, or skin antiseptics, would be placed in Category I as first aid antiseptics. Povidone-iodine and camphorated phenol also would be moved from Category III (as skin antiseptics) to Category I (first aid antiseptics). Based on data contained in comments to the previous monograph, the FDA also would place hydrogen peroxide, camphorated metacresol (3% to 10.8% camphor and 1% to 3.6% metacresol in a ratio of 3:1), and a combination product containing equcalyptol 0.091%, menthol 0.042%, methyl salicylate 0.055%, and thymol 0.063% into Category I.

Soaps containing antimicrobial ingredients would be considered cosmetics when deodorancy or other cosmetic claims are the only claims made for the product.

The indications "prevents skin infection," "controls infection," "degerming," "kills germs," "bacteriostatic," "bactericidal," "reduces the risk of infection and cross-infection," and "microbiocidal" would be eliminated.

The phrase "after gentle washing with soap and water" would be deleted, as alkaline soap may be inappropriate for use on damaged tissue.

The label "alcohol for topical antimicrobial use" would be changed to "first aid antiseptic" to be consistent with other first aid antiseptics. The warning "Use only in a well-ventilated area; fumes may be toxic" would be deleted on products containing isopropyl alcohol.

The minimum concentration of povidone-iodine for effectiveness would be reduced from 7.5% to 5%. The FDA also is proposing that the two-year expiration date for iodophors be eliminated, and that povidone-iodine be reclassified for first aid antiseptic use to Category I.

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These proposed changes would go into effect July 22, 1992. Antiseptic handwashes and chlorhexidine gluconate (marketed for professional or hospital use as a first aid solution) were not addressed in this monograph, as the FDA felt they were not OTC topical first aid products. They will be the topics of future monographs.

Diseases Storm Through Iraq

As a result of the Gulf War, Iraq water purification plants, sewage disposal plants, and power systems sustained heavy bombing, and infectious diseases are increasing because of water system contamination, according to Michael Viola, MD, from State University of New York, Stony Brook, New York.

"Children seem to be suffering the most," said Viola, who also is the codirector of Medicine for Peace.

A Medicine for Peace team, which included Lewis Marshall, MD, from Washington, D.C., William Lipera, from Stony Brook, New York, Viola, and a Medicine for Peace film crew returned from Iraq on June 18, 1991.

"The diseases we saw most frequently and that are in epidemic proportions are chronic diarrhea in children, typhoid fever, meningitis, and viral hepatitis. Cholera cases also are more frequent than in the past. We're starting to see cases of polio, measles, and mumps in a group of children who were not vaccinated because of the war and because there are no vaccines in Iraq right now," Viola said.

These diseases were better controlled a year ago, he added.

The crippled state of the healthcare system is ailing as rapidly as the people it serves. Because of the medical embargo by UN sanctions, hospitals are running out of antibiotics. They already have run out of vaccines and most other medicines.

To make matters worse, most of the equipment in hospitals is now in disrepair because spare parts also are embargoed. "The problem is we have all this infectious disease, and there is no way to take care of it because the hospitals are barely functional," Viola said.

"Individual care is being seriously jeopardized. There are physicians who do not have antibiotics or syringes. There are people using syringes over again; they have all been boycotted. When we were there it was 120" in the afternoon. In the wards, it was 110 because freon (used in air conditioners) has been embargoed.

'We witnessed the closing of the major pediatric hospital of Baghdad University. The whole system is collapsing. The medical care system there, which at one time was very good, is completely incapable of taking care of the present medical crisis," said Viola.

A lack of infant formula also is leading to diseases from malnutrition.

"There has been no formula that has come into the country since August 2, 1990, with the exception of a very small amount that was sent by humanitarian organizations," said Viola.

Not only is the shortage of infant formula a problem, but the children are suffering with chronic diarrhea and cannot tolerate breast milk.

"They become lactose intolerant," Viola explained, "so they need a modified formula, which you could get in any drug store in this country but that has been embargoed in Iraq, so the kids are starving to death there."

From ***Infectious Diseases in Children.*** August 1991;4:1.

Dental Amalgam Fillings May Increase Antibiotic Resistance

The release of mercury from dental amalgam fillings increases the incidence of mercury resistance and antibiotic resistance among the common bacteria that inhabit the mouth and intestine, according to Anne 0. Summers, MD, from The University of Georgia, Athens, Georgia.

'Within two weeks after the installation of amalgam fillings in each of four monkeys, a large proportion of their oral and intestinal bacteria had become resistant to mercury, and 80% of these bacteria were also resistant to one or more antibiotics," said Summers.

"These are controlled, laboratory experiments," Summers cautioned, "and further investigation is needed to determine whether amalgam fillings cause the high incidence of mercury-resistant bacteria that can occur among the intestinal bacteria of humans."

It was once believed that mercury was not released from dental amalgam, she noted, "but it is now well documented that these fillings are the major source of mercury exposure for humans, amounting typically to 10 μg per day."

For comparison, only about 0.6 μg is available from the food people consume daily, she said.

In the initial study reported, bacterial samples were obtained from two monkeys during the ten days before and for 30 days after the installation of the amalgam fillings. The monkeys excreted about 300 μg per day of mercury in their feces and were found to have high levels of mercury in their kidneys, liver, and pituitary glands.

In the subsequent five-month study with a second