KELLER AND HECKMAN LLP
Serving Business through Law and Science®

1001 G Street, N.W.
Suite 500 West
Washington, D.C. 20001
tel. 202.434.4100
fax 202.434.4646

Writer's Direct Access
Herbert Estreicher
(202) 434-4334
estreicher@khlaw.com

November 13, 2006

Via Facsimile and Electronic Submittal

Clerk of the Board
Air Resources Board
1001 I Street, 23rd Floor
Sacramento, California 95814
Facsimile: (916) 322-3928

Re: Comments on the Proposed 2006 Amendments to the California Consumer Products Regulations

Dear Board Members:

On behalf of our client, NicePak, Inc. (hereinafter, NicePak), we hereby submit the following comments in response to the California Air Resources Board (CARB) *Proposed Amendments to the California Consumer Products Regulations* (CCPR).[1] NicePak is a leading manufacturer and distributor of pre-moistened wipes used in a broad spectrum of applications including use in disinfectants, sanitizers, healthcare products, cosmetics and personal hygiene products. As such, NicePak products sold or distributed in California are potentially subject to CARB's proposal to further restrict volatile organic compound (VOC) concentrations in consumer products.

In particular, the proposed 1% VOC content limit for non-aerosol disinfectants and sanitizers would effectively ban from sale or distribution in California, NicePak's Sani-Wipe® No-Rinse Hard Non-Porous Surface Sanitizing Wipes (hereinafter "Sani-Wipes"), which contains 5.48% isopropanol as an active sanitizing ingredient.[2] As the attached memorandum from the Food and Drug Administration (FDA) indicates, Sani-Wipes are one of only two products recognized by the FDA as appropriate for use as a no-rinse spot sanitizer on food contact surfaces. A companion to the Sani-Wipe product, Sani-Cart Wipe™, which is sold to grocery stores for use by store customers on shopping cart handles and child seats that may be contaminated by dirty hands, dirty diapers, and leaky fresh meat or poultry packages, also would be banned by the 2006 Amendments to the CCPR because of isopropanol. Neither Sani-Wipes

[1] September 19, 2006, version for 45-day public comment period available from http://www.arb.ca.gov/regact/cpwg2006/appenb.pdf.

[2] *Id.* at § 94509(a).

nor Sani-Cart can be reformulated to remove the isopropanol and still retain their unique benefits to the consumer.

Recent reports suggest that harmful bacteria from shopping cart handles may present an exposure risk to infants and others.[3] Pre-moistened wipes are the only effective means consumers are likely to use to sanitize/disinfect this exposure pathway because of the convenience offered by wipes. Consumers are not likely to use spray or aerosol solutions in the store setting and certainly will not dip their hands in a bucket of chemical solution to use the traditional "wet rag" method. Sanitizing/disinfecting solutions and rags or cloths become dirty and ineffective after repeated use. They also pose potential spill hazards and present other logistical concerns that make their in-store use less than desirable. In contrast, pre-moistened sanitizing/disinfecting wipes are easy to use and can readily be mounted near a shopping cart or baby seat distribution area. In addition, pre-moistened wipes always deliver the same quantity and concentration of clean sanitizing/disinfecting solution, thereby enhancing customer safety by reducing overspray or dilution errors.

The above-discussed unique advantages and critical benefits are inextricably linked to the no-rinse characteristics of these pre-moistened wipe products. In turn, this critical characteristic depends on the volatility of the alcohol active ingredients. Isopropanol has been recognized by FDA as an ideal antimicrobial agent which poses almost no residual toxicity to the end user.

The continued use of isopropanol and other alcohols in food contact sanitizing wipes, which effectively would be banned by the 2006 CARB amendments, for example, is critical in part because the no-rinse characteristics of these products cannot be achieved without volatilization. Phenols, such as triclosan and triclocarbon, and quaternary ammonium and the other substances CARB identified as typical non-aerosol sanitizer ingredients simply do not provide the requisite volatility for sanitizing wipes to meet FDA Food Code Requirements. These other substances may also raise other concerns such as resistance and, in some cases, health-related concerns.

On October 20, 2005, the Food and Drug Administration's (FDA's) Nonprescription Drugs Advisory Committee (NDAC) held a meeting to review the use of over-the-counter (OTC) antiseptic drug products by general consumers.[4] The focus of the meeting was solely on the use

[3] *See e.g.*, Fullerton, K.E. et al, Risk Factors for Infant Campylobacter Infections: A FoodNet Case-Control Study, Abstract Submission presented at 43rd Annual Meeting of the Infectious Diseases Society of America (riding in shopping cart identified as risk factor); *see also*, MSNBC, *Eww! Shopping cart handles loaded with germs*, February 14, 2006 at http://www.msnbc.msn.com/id/11343972/.

[4] 70 *Fed. Reg.* 54560 (September 15, 2005) (meeting announcement).

of products such as hand sanitizers in consumer settings (*e.g.*, home or day care). In the end, the Committee voted to impose a requirement that these OTC products be shown to have an effect on reducing infection in the target population (not just that they kill germs on the skin). (*See* attached.) The one exception was "alcohol-based" antiseptic products, which the Committee agreed provided a benefit in the absence of, or when it is very inconvenient to access, soap and water. The NDAC recommendation serves further to attest to the importance of alcohol-based sanitizers and disinfectants.

Given the above considerations and the recognized health and food safety benefits from using pre-moistened alcohol-based wipes, NicePak respectfully requests that CARB provide an exemption from the 1% VOC content limit for such products. As CARB itself determined, "most of the non-aerosol sanitizers are liquid products that require dilution with water. Additional product forms include, foam, and mist spray dispensed via a non-pressurized system."[5] Thus, this exemption would apply to a very limited number of products and would not measurably affect VOC emissions in the state.

If you have any questions, do not hesitate to contact the undersigned.

Respectfully submitted,

Herbert Estreicher
Counsel to NicePak, Inc.

Enclosures

cc: David Jones, NicePak, Inc.
Clyde Noel, NicePak, Inc.
David Mallory, California Air Resources Board

[5] California Air Resources Board, Initial Statement of Reasons for Proposed Rulemaking; Technical Support Document, VI-52.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: September 8, 2003

From: CFSAN Retail Food Protection Team

Subject: Hard Surface Sanitizer Wipes

To: FDA Regional Food Specialists

There are products being marketed to the food service and retail food industry known as hard surface sanitizing wipes or sanitizer wipes. Food establishment operators and regulatory personnel have raised questions about how the Food Code addresses the appropriate use of sanitizer wipes in food establishments. While the Food Code does not make specific reference to sanitizer wipes, it does contain information that can help answer many of the questions being asked.

1. Can sanitizer wipes be used to sanitize food-contact surfaces?

When used in accordance with the manufacturer's instructions, EPA-registered sanitizer wipes have demonstrated the ability to deliver the minimum five-log pathogen reduction specified in the Food Code for the sanitization of cleaned hard surfaces. The sanitizer concentrations in products registered with EPA for food-related uses are consistent with Federal regulation. Therefore, these sanitizing wipes may be used to sanitize food-contact surfaces that have been cleaned in accordance with Food Code.

To be acceptable for use as an effective sanitizing method for food-contact surfaces, sanitizer wipes must conform to EPA registration and labeling requirements and FDA Food Code requirements for:

- The type, concentration, and temperature of the chemical solution used, including conformance with the regulations in 21CFR 178.1010 *Sanitizing solutions*; and
- The necessary exposure time (i.e., the time that surfaces remain wet with the sanitizer).

FDA is aware of two EPA-registered sanitizer wipes on the market that conform to these requirements: Sani-Wipe® No-Rinse Hard Non-Porous Surface Sanitizing Wipes (distributed by PDI Products, Inc) and Kimtech Prep Surface Sanitizer Wipes (distributed by Kimberly-Clark Professional). Please note that there are wipes on the market with similar names that do not meet these requirements and are not labeled for use on food-contact surfaces. It is important to read the product label.

2. Can sanitizing wipes be used to clean food-contact surfaces?

The Food Code requires that food-contact surfaces and utensils be clean to sight and touch prior to being sanitized. Depending upon the chemical formulation of the wipe solution, the nature of food soils on a surface, and the type and configuration of the food-contact surface,

the use of sanitizer wipes may be an effective method for getting lightly soiled surfaces clean to sight and touch. After a surface has been cleaned using one or more wipes, a new wipe or wipes should be used to sanitize the surface. If sanitizer wipes are used to clean and sanitize a surface, it is not necessary to include a rinse step between the cleaning and sanitizing steps.

3. Are there certain types of food-contact surfaces that should not be cleaned or sanitized with sanitizer wipes?

The sanitizer wipes currently registered by EPA are intended for use on hard, nonporous surfaces only. There are many types of equipment and utensils that, due to their configuration or type of soiling, do not lend themselves to proper cleaning or sanitizing with a wipe alone and for which mechanical or manual warewashing, brushing, pressure spraying, clean-in-place systems, or other methods are necessary. EPA's Division of Antimicrobials is reviewing its current labeling requirements to determine the most appropriate use restrictions and to ensure that the instructions are clear to the user. At EPA's request, FDA is assisting in this review. Sanitizer wipes must be used in accordance with the instructions and use limitations on the EPA-approved product label.

4. Can sanitizer wipes be used as wiping cloths for wiping food spills?

Disposable, pre-moistened wipes are an acceptable alternative to a dry wiping cloth or a wet wiping cloth stored in a chemical sanitizer between uses. The Food Code specifies that a pre-moistened wipe used to wipe food spills be discarded after use and not be used for any other purpose. If used on food-contact surfaces, the concentration of any sanitizing solution in the wipes shall conform to Food Code section 7.204.11.

5. Can sanitizer wipes be used on nonfood-contact surfaces?

The Food Code does not establish requirements related to the methods used to clean or maintain nonfood-contact surfaces. Operators should refer to the product label to determine the proper use of wipes on floors, walls, dining areas, bathrooms, and other nonfood-contact areas where food is not prepared or stored.

For more information, please contact Kevin Smith, FDA Retail Food Protection Team, at (301) 436-1498.

October 20-21, 2005
Meeting of the Nonprescription Drugs Advisory Committee

Open Public Hearing Speakers (October 20, 2005):
Sally Bloomfield, M.D., Pfizer
Lawton Seal, Healthpoint, LTD
Denise Graham, Association for Professionals in Infection Control and Epidemiology, Inc
Howard Bochnek, Veriden Coorporation
Donald A. Goldmann, M.D. Self-Interest
Eugene C. Cole, DrPh, Self-Interest

On October 20, 2005, the committees discussed the benefits and risks of antiseptic products marketed for consumer use (e.g., antibacterial hand-washes and body-washes). The discussion included topics such as; the efficacy of antiseptics intended for use by consumer, and potential risks to the individual and the general population from using these products.

Alastair Wood, M.D. (Committee Chair), called the meeting to order at 8:00 a.m. The Committee members, consultants, and FDA participants introduced themselves. The conflict of interest statement was read into the record by Darrell Lyons B.S.N. The agenda proceeded as follows:

Welcome and Introductory Comments	Susan S. Johnson, Ph.D., Acting Director Division of Nonprescription Regulation Development Office of Nonprescription Products, CDER
FDA Presentations:	
Regulatory History and Attributes of Consumer Antiseptic Drug Products	Colleen Rogers, Ph.D., Microbiologist Division of Nonprescription Regulation Development, ONP, CDER
Clinical Benefit of Consumer Antiseptics	Steven Osborne, M.D., Medical Officer Division of Nonprescription Clinical Evaluation ONP, CDER
Community-based Studies of Consumer Antiseptics	Allison E. Aiello, Ph.D., M.S., Assistant Professor Center for Social Epidemiology & Population Health Department of Epidemiology University of Michigan School of Public Health Ann Arbor, MI
The Potential for Antibiotic/ Biocide Cross-resistance	Stuart B. Levy, M.D., Professor Department of Molecular Biology & Microbiology Tufts University School of Medicine Boston, MA
Secondary Routes of Exposure to Biocides	Rolf U. Halden, Ph.D., P.E., Assistant Professor Center for Water and Health Department of Environmental Health Sciences Johns Hopkins Bloomberg School of Public Health Baltimore, MD
EPA Regulatory Process for Antimicrobials	Mark Hartman, Branch Chief Regulatory Management Branch Antimicrobials Division Environmental Protection Agency

October 20-21, 2005
Meeting of the Nonprescription Drugs Advisory Committee

Sponsor Presentations:

Introduction	Elizabeth H. Anderson Associate General Counsel The Cosmetic, Toiletry, and Fragrance Association, Washington D.C.
Laboratory Studies: Resistance/ Cross-resistance Development in Transmission of Infectious Diseases	Peter Gilbert, B.Sc., Ph.D. Professor of Microbial Physiology Medical Director, Hospital Epidemiology Professor of Medicine, Pediatrics & Epidemiology University of North Carolina at Chapel Hill
Importance of Fomites in the Transmission of Infectious Diseases	Charles P. Gerba Department of Soil, Water and Environmental Science and Epidemiology and Biostatics University of Arizona, Tucson, AZ

Open Public Hearing Presentations

Questions to the Committee:

1. **As drug products, should consumer antiseptics be expected to provide clinical benefit by reducing infection (vote)**
   Yes: 12
   No: 0
   Abstain: 0

2. **Based on the information in the background materials and today's presentations, are there any populations, outside of the healthcare setting, in which consumer antiseptic use has been demonstrated to be more effective than use of plain soap in reducing infection rates? (vote)**

   If yes, please describe the population and the category of consumer antiseptic that provided benefit (e.g., antiseptic hand-wash, antiseptic body-wash, hand sanitizer).

If no, what criteria should be used to define a consumer population for which washing with plain soap and water, or other hygiene measures that do not involve antiseptic drug products, are inadequate to reduce infection risk?

Yes: 1
No: 11
Abstain: 0

Discussion:
The committee agreed that studies should be conducted on populations in which there was increased risk of/or transfer of infection (e.g., immune suppressed, diarrhea, upper respiratory infection) or co-morbidity. See transcript for further discussion.

3. **Earlier this year, NDAC met to discuss the efficacy criteria for healthcare antiseptic drug products and accepted clinical simulation testing as a surrogate for bacterial infection rate to measure efficacy of healthcare antiseptics. What type of studies/endpoints should be used to establish efficacy in populations that require consumer antiseptics?**

Discussion:
See transcript for complete discussion.

4. **As with many drugs, the use of consumer antiseptics may be associated with a number of adverse consequences. The extent, to which these consequences are attributable to consumer antiseptics, and the importance of the consequences to public health, are varied. How should each of the following be factored into FDA's decisions about product regulation?**

   a. **Application site consequences for the individual user (e.g., local Irritation, dryness).**

      Discussion:
      The committee agreed consequences for the individual user (e.g., local irritation, dryness, etc,) is important but not life-threatening. The committee recommended using labeling to address these issues.

   b. **Systemic consequences for the individual user (e.g., incomplete immune system development, development of antibacterial resistance in the individual).**

      Discussion:
      The committee agreed that to find evidence of harm would require long-term surveillance that would be very difficult to study and there would probably be funding issues.

   c. **Societal consequences associated with chronic exposure of the environment to consumer antiseptics (e.g., widespread development of antibacterial resistance, antiseptic impact on ecosystems, secondary exposure to humans).**

      Discussion:
      The committee suggested that the FDA require studies of benefit of these products over and above alcohol base products and soap and water.

The meeting was adjourned at approximately 4:20 p.m. October 20, 2005.

Executive Secretary Chair