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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Cincinnati District Office
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WARNING LETTER

CIN-WL-07-34157-19

September 14, 2007

Alan G. Lafley
President and Chief Executive
Procter and Gamble
One Procter and Gamble Plaza
Cincinnati, Ohio 45202

Dear Mr. Lafley:

This letter concerns your firm's labeling and marketing of the product "Vicks Early Defense Foaming Hand Sanitizer." As presently labeled and promoted, this product violates provisions of the Federal Food, Drug, and Cosmetic Act (the Act) as described below.

As described in more detail below, the product labeling includes statements that direct consumers to use the product in a manner that is inconsistent with labeling allowed under FDA's OTC Drug Review.

The Drug Facts Format portion of the label lists the active ingredient as 0.1% triclosan. The directions for use on the label for children 2 to under 12 years of age, and adults and children 12 years of age and over, state "wet hands thoroughly with product and allow to dry without wiping." The directions for use section also states "use anytime when soap and water are not readily available." In addition, the product label includes the statement:

"Foaming hand sanitizer helps fight germs for up to 3 hours* under laboratory conditions."

According to your internet website (www.vicks.com), which is referenced on the package label, the product is intended for topical antimicrobial uses to prevent disease. The following statements on your website demonstrate your product's intended uses:

"Fighting Colds - - Wash Your Hands - - The surest way to catch a cold is to catch the germs that cause the cold. Frequent hand washings help eliminate germs and keep you and your family healthy....Between hand washings, when soap and water are not available, use Vicks Early Defense Foaming Hand Sanitizer to kill 99.9% of germs. Vicks Early Defense Foaming Hand Sanitizer helps fight germs for up to three hours* under laboratory conditions."

"Vicks Defense Tips - - You're Not Defenseless - - You've caught a cold. How do you make sure you don't infect friends and family? *** Simply follow these tips and stock your cabinet with Vicks Early Defense *** Keep Germs to Yourself * * * Always wash your hands after sneezing,

blowing your nose, coughing, or touching used tissues. Don't have access to soap and water? Use Vicks Early Defense Foaming Hand Sanitizer to kill 99.9% of germs. Vicks Early Defense Foaming Hand Sanitizer helps fight germs for up to three hours* under laboratory conditions."

Vicks Early Defense Foaming Hand Sanitizer is a "drug," as defined by section 201(g)(1) of the Act (21 U.S.C. § 321(g)(1)), because it is intended to prevent disease, as described above. In addition, the product is a "new drug," as defined by section 201(p) of the Act (21 U.S.C. § 321(p)), because we are not aware of sufficient evidence to show that it is generally recognized as safe and effective for the labeled uses. In particular, we are not aware of evidence establishing that this product is safe and effective in preventing colds as claimed in the product labeling. Under sections 301(d) and 505(a) of the Act (21 U.S.C. §§ 331(d) and 355(a)), a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA approved application is in effect for it. Vicks Early Defense Foaming Hand Sanitizer does not have an approved application, and its introduction and delivery for introduction into interstate commerce violates these provisions of the Act.

For your information, OTC health care antiseptics, which include antiseptic cleansers, and OTC first aid antiseptics are being evaluated under FDA's OTC Drug Review. Tentative final monographs (TFMs) for these products were published in the Federal Register of June 17, 1994 (59 FR 31402) and July 22, 1991 (56 FR 336444). These TFMs are available on FDA's Internet website at www.fda.gov/cder/otcmonographs/category_sort/antimicrobial.htm. Although the active ingredient in Vicks Early Defense Foaming Hand Sanitizer, i.e., triclosan, is covered by these ongoing rulemakings for certain topical antimicrobial uses, the claims referenced above and the directions to "leave-on" without rinsing with water are not.

The directions for use state that the product is to be applied to the hands and allowed to dry without wiping. The directions for use do not instruct the user to rinse with water after application. Although triclosan as an antimicrobial hand cleanser, followed by a water rinse, is deferred to the FDA's OTC Drug Review, in a leave-on liquid form for use without rinsing, it is not. In addition, since we are not aware of any marketing of a "leave-on" product formulated and labeled like Vicks Early Defense Foaming Hand Sanitizer on or before the inception of the OTC Drug Review, it is not deferred to the OTC Drug Review.

Furthermore, the product claims to be effective in fighting the "germs" that cause colds. We are not aware of sufficient evidence to show that that the product is generally recognized as safe and effective in preventing individuals from becoming infected with colds, a condition caused by viruses. We are also not aware of any marketing of a product formulated and labeled like Vicks Early Defense Foaming Hand Sanitizer offered for the prevention of colds on or before the inception of the OTC Drug Review. Thus, the product is not deferred to the OTC Drug Review for that indication.

Pending a final monograph for OTC health care antiseptics, we would not object to the marketing of a triclosan-containing OTC antiseptic handwash provided that it is formulated and labeled in accordance with the conditions covered under the OTC Drug Review. Such marketing, however, is subject to the risk that a final monograph or rule may require reformulation and/or relabeling or FDA approval through the "new drug" procedures of the Act (section 505).

The above violations are not intended to be an all-inclusive list of deficiencies with your product. It is your responsibility to assure that your firm's operations and controls adhere to all requirements of federal law and FDA regulations.

Vicks Early Defense Warning Letter CIN-07-34157-19

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction. Other federal agencies may take this Warning Letter into account when considering the award of contracts.

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct the referenced violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction. Your reply should be directed to: Stephen J. Rabe at the address listed in the letter head or at 513-679-2700 ext.163. If you have any questions concerning this letter, you may contact Mr. Rabe.

Sincerely,

A handwritten signature in cursive script, appearing to read "Carol A. Heppe".

Carol A. Heppe
District Director