



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Atlanta District Office

91195

60 8th Street, N.E.  
Atlanta, Georgia 30309

March 29, 2001

**VIA FEDERAL EXPRESS**

Daniel S. Hirsh  
President  
Perfecto Products Manufacturing, Inc.  
1800 Marietta Blvd. NW  
Atlanta, Georgia 30318

**WARNING LETTER**  
**(01-ATL-37)**

Dear Mr. Hirsh:

An inspection of your drug manufacturing facility was conducted on November 29 and December 6, 2000, by Investigator Leah M. Andrews of this office. The inspection revealed significant violations of the "new drug" (section 505) and misbranding (section 502) provisions of the Federal Food, Drug, and Cosmetic Act (the Act), as described below. The inspection also revealed significant deviations, detailed below, from the Current Good Manufacturing Practice for Finished Pharmaceuticals (CGMPs) under Title 21 of the Code of Federal Regulations, Part 211 (21 CFR 211). These CGMP deviations cause your drug products, such as *PERFECTO tricolan* and *PERFECTO HALT*, to be adulterated as described by section 501(a)(2)(B) of the Act.

Labels for the following products, which are currently manufactured or repackaged by your firm, were collected during the inspection referenced above:

*PERFECTO SHIELD*  
*PERFECTO tricolan ANTIMICROBIAL SOAP*  
*PERFECTO HALT*  
*PERFECTO PROFESSIONAL HAND TREATMENT*  
*PERFECTO MICROBAN 4% CHG SCRUB*

The labels were reviewed by FDA's Center for Drug Evaluation and Research, Office of Compliance. The issuance of this letter has been withheld pending the review. That office has determined that such labels cause these products to be in violation of the Act as follows:

PERFECTO SHIELD

The label for this product includes words and statements such as "SHIELD," "PROFESSIONAL SKIN PROTECTION," and "PROTECTS HANDS FROM: CEMENTS, ADHESIVES, SOAPS, DETERGENTS, ALCOHOLS AND OTHER IRRITANTS," which represent or suggest that *PERFECTO SHIELD* is intended to form a barrier on the skin to prevent adverse effects caused by contact with skin irritants. Based on these disease-prevention claims, this product is a "drug" as defined by section 201(g) of the Act.

We are not aware of any substantial scientific evidence that this product is generally recognized by scientific experts as safe and effective for these uses, which are not being considered in any of the rulemakings under FDA's Over-The-Counter (OTC) Drug Review. Thus, *PERFECTO SHIELD* is a "new drug" as defined by section 201(p) of the Act. Because this product is not the subject of an FDA-approved new drug application (NDA) and it is currently marketed by your firm in the United States, it violates section 505(a) of the Act. In addition, since the adequacy of the labeled directions for use has not been determined, this product is misbranded under section 502(f)(1) of the Act.

This drug is further misbranded under sections 502(e) and 502(o) of the Act, because the label does not disclose the names of any active ingredients and the product is not listed with FDA as required by section 510 of the Act, respectively.

PERFECTO tricolan ANTIMICROBIAL SOAP

The label for this product includes words and statements such as "ANTIMICROBIAL SOAP," "DENTAL HEALTH CARE PERSONNEL HANDWASH," "TRICOLAN CONTAINS PCMX, A BROAD-SPECTRUM ANTIMICROBIAL INGREDIENT REDUCING RISK AND-OR CHANCE OF CROSS-INFECTION," and "During washing, a thin deposit of emollient and PCMX is left on the skin, giving protection from chapping and irritation," which represent or suggest that *PERFECTO tricolan ANTIMICROBIAL SOAP* is intended to have an antimicrobial effect on the skin, while also providing a skin protectant effect, to thereby prevent disease. Based on these disease-prevention claims, this product is a "drug" as defined by section 201(g) of the Act.

We are not aware of any substantial scientific evidence that chloroxylenol for skin protectant uses, or that the combined antimicrobial soap and skin protectant uses for this product are generally recognized by scientific experts as safe and effective for skin protectant uses. Chloroxylenol, which is the sole active ingredient declared on the label as "PCMX (para-chloro-meta-xylenol)," is covered by FDA's OTC Drug Review for antimicrobial soap use, but it is not being considered for any skin protectant uses. The combined antimicrobial soap and skin protectant uses are also not being considered under the Review. Thus,

*PERFECTO tricolan ANTIMICROBIAL SOAP* is a “new drug” as defined by section 201(p) of the Act. Because this product is not the subject of an FDA-approved new drug application (NDA) and it is currently marketed by your firm in the United States, it violates section 505(a) of the Act. In addition, since the adequacy of the labeled directions for use has not been determined, this product is misbranded under section 502(f)(1) of the Act.

This drug is also misbranded under sections 502(e) and 502(o) of the Act, because the label does not identify “PCMX” or “para-chloro-meta-xyleneol” by its established name, i.e., chloroxylenol, and this product is not listed with FDA as required by section 510 of the Act, respectively.

#### *PERFECTO HALT*

The label for this product includes words and statements such as “Healthcare Personnel Antiseptic Hand Rinse,” which represent and suggest that it is intended to prevent diseases caused by microorganisms. Based on these disease-prevention claims, this product is a “drug” as defined by section 201(g) of the Act. *PERFECTO HALT* is misbranded under section 502(o) of the Act because it is not listed with FDA as required by section 510.

#### *PERFECTO PROFESSIONAL HAND TREATMENT*

The label for this product includes words and statements such as “This product contains a broad spectrum antimicrobial agent,” which represent and suggest that it is intended to prevent diseases caused by microorganisms. Based on these disease-prevention claims, this product is a “drug” as defined by section 201(g) of the Act. *PERFECTO PROFESSIONAL HAND TREATMENT* is misbranded under sections 502(e) and 502(o) of the Act, because the label does not identify the active antimicrobial ingredient and this product is not listed with FDA as required by section 510 of the Act, respectively.

#### *PERFECTO MICROBAN 4% CHG SCRUB*

The label for this product includes words and statements such as “MICROBAN,” “ANTIMICROBIAL SOLUTION,” “SURGICAL SCRUB,” and “HEALTH CARE PERSONNEL HANDWASH,” which represent and suggest that it is intended to prevent diseases caused by microorganisms. Based on these disease-prevention claims, this product is a “drug” as defined by section 201(g) of the Act.

*PERFECTO MICROBAN 4% CHG SCRUB* is a “new drug” as defined by section 201(p) of the Act since this product’s active antimicrobial ingredient (chlorhexidine gluconate) is not generally recognized as safe and effective for any topical antimicrobial uses.

Because the labeling for this product is not the subject of an FDA-approved new drug application (NDA) and it is currently marketed by your firm in the United States, it violates section 505(a) of the Act. This product does not bear labeling approved under any NDA. We note that the labeling for *PERFECTO MICROBAN 4% CHG SCRUB* does not bear all of the warnings, a "WARNINGS" heading, or a statement of identity that are presently required for such products under the NDA provisions of the Act. In addition, since the adequacy of the labeled directions for use has not been determined, this product is misbranded under section 502(f)(1) of the Act.

Regarding the CGMP deviations observed during the inspection referenced above, you could provide no assurance that your products met the identity, purity, and quality claims made on their labeling. Each batch of drug product must have appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of the active ingredient(s), prior to release. You conducted assay testing on only three of the last nine lots of Tricolan produced. You have never tested your Halt product lots for identity and strength.

You could provide no assurance that your drug products meet applicable standards of identity, strength, quality, and purity at their time of purchase and throughout their expected period of use. You had failed to establish a written stability testing program to assess the stability characteristics of your drug products. This testing is necessary to determine appropriate storage conditions and expiration dates. You could provide no stability test results for any of the products you manufacture or repack. None of your manufactured products bear an expiration date as required. You have also failed to justify the expiration date currently placed on your repacked lots.

You have failed to establish adequate written procedures describing in sufficient detail the receipt, identification, handling, sampling, testing, and approval or rejection of components and drug product containers and closures. The procedures on file do not require that raw materials be inspected prior to use or that a Certificate of Analysis accompany the material, if applicable. At least one test must be conducted to verify the identity of each component of a drug product. Specific identity tests, if they exist, must be used. Each component must be tested for conformity with appropriate written specifications prior to use. A Certificate of Analysis may be accepted from a supplier, provided that at least one specific identity test is conducted on the component and you have established the reliability of the supplier's analyses. Your procedures also do not require incoming bottles and closures to be inspected which includes bottles with preprinted labeling.

You were not following your own procedures for incoming components, as you were not recording the limited information called for to document the receipt of raw materials. There was no indication that the products had been visually examined upon receipt. Your procedures require the sampling and testing of incoming containers and closures. This information was not being recorded. Your procedures did not include a

description of the actual number of containers to be tested or the acceptance criteria. Additional controls must be in place for containers that contain preprinted labeling. There was no documentation available to indicate that this labeling had been reviewed or compared to master labeling records prior to release.

Another example of your firm's failure to adequately test components is the lack of testing of the deionized water system at your facility. Although periodic testing was implemented after the previous inspection, no testing has been conducted since March of 1998.

You have failed to establish appropriate written procedures to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. In addition to the discrepancies discussed above, there were no procedures addressing the retesting of raw materials, the investigation of any out-of-specification results, the inspection and control of labeling, training of employees, and distribution of your drug products.

Your facility did not have clearly defined storage areas for the storage of raw materials and finished products. An examination of the warehousing area revealed rejected goods stored immediately adjacent to released raw materials.

The violations cited in this letter are not intended to be a statement of all the violations that may exist for products marketed by your firm. It is your responsibility to assure that all your products are in compliance with federal laws and regulations. The above deviations were included on the Inspectional Observations (FDA 483) which was issued to and discussed with you at the conclusion of the inspection. The specific violations noted in this letter and in the FDA 483 could be symptomatic of underlying problems in your firm's quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

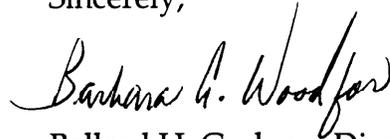
Federal agencies are advised of the issuance of all warning letters about drugs so that they may take this information into account when considering contract awards. Additionally, pending New Drug Applications, Abbreviated New Drug Applications, or export approval requests may not be approved until the above violations are corrected. Failure to promptly correct these violations may result in regulatory action without further notice. Such actions include seizure and/or injunction.

Within fifteen (15) working days of your receipt of this letter, please notify this office in writing of the specific steps you will take to correct the noted violations. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should include your plans concerning the distribution of the drug products discussed above.

Of particular concern is the fact that many of the above CGMP violations were pointed out to you during the previous inspection conducted in February 1996. These include the failure to test finished product, lack of a stability testing program, inadequate control of components, and deficient testing of the water system. Although improvements had been noted during the previous inspection, you have not remained diligent in bringing your firm into compliance.

We are in receipt of your responses dated January 11 and February 18, 2001, to the FDA 483. These responses were reviewed by Investigator Andrews. Although your responses were at times vague and failed to include any actual new procedures, you did address the major items on the FDA 483. There was no mention of an ongoing stability program in your responses. You also did not address what specific identity tests would be performed. Your reply to this letter should be sent to the Food and Drug Administration at the above letterhead address to the attention of Philip S. Campbell, Compliance Officer.

Sincerely,

A handwritten signature in cursive script that reads "Barbara A. Woodford".

Ballard H. Graham, Director  
Atlanta District