Inspections, Compliance, Enforcement, and Criminal Investigations

Johnson & Johnson Consumer Group of Companies, Inc. 9/27/10

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 331-4906

September 27, 2010

WARNING LETTER

HAND DELIVERED

Mark Bowden
Vice President of Global Regulatory Affairs
Johnson and Johnson Consumer Products, Inc.
199 Grandview Road
Skillman, New Jersey 08558-1303

10-NWJ-17

Dear Mr. Bowden:

This letter is in reference to the Listerine Total Care Anticavity Mouthwash distributed by your firm. The label for this product makes the following claims: "Strengthens Teeth, Restores Minerals to Enamel, Fights Unsightly Plaque Above th Gum Line, Helps Prevent Cavities, Kills Bad Breath Germs, and Freshens Breath."

Based on these labeled claims "Fights Unsightly Plaque Above the Gum Line" and "Prevents Cavities," Listerine Total Care Anticavity Mouthwash is a drug as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act (Act) (21 U.S.C. § 321(g)) because the product is intended for use in preventing or mitigating disease, or to affect the structure or function of the body, by preventing cavities and removing plaque. Sodium fluoride 0.0221% (0.01% w/v fluoride ion) for the purpose of "Anticavity" is the sole active ingredient listed for this product. This product is subject to the Final sole active ingredient listed for this product. This product is subject to the Final Monograph for Anticaries Drug Products for Over-the-Counter Use, 21 CFR Part 355, which covers the product's disease claim of helping "prevent cavities," and includes this active ingredient.

However, another claim on the label of Listerine Total Care Anticavity Mouthwash is "Fights Unsightly Plaque Above the Gum Line." This statement represents that the product fights plaque, a well-known precursor to gum disease, including gingivitis. Antiplaque/antigingivitis claims are not covered by the Anticaries Final Monograph. Such antiplaque/antigingivitis claims are, however, addressed in the Advanced Notice of Proposed Rulemaking (ANPR) for Ora Healthcare Products for antigingivitis/antiplaque (68 Fed. Reg. 32232 (May 29, 2003)). In that ANPR, the agency identified active ingredients under consideration for inclusion in an antigingivitis/antiplaque monograph; however, sodium fluoride is not among them.

Thus, no mouthwash with sodium fluoride as the active ingredient has been included or proposed for inclusion in any monograph for the antiplaque/antigingivitis indications claimed for Listerine Total Anti-cavity Mouthwash; that ingredient is not included among those under evaluation in the ANPR for antiplaque/antigingivitis drug products, nor does the anticaries monograph at 21 CFR part 355, which does include the active ingredient of sodium fluoride, include antiplaque claims as recognized claims. As formulated and labeled, Listerine Total Anticavity Mouthwash is not generally recognized as safe and effective for the antiplaque indications in its labeling, and it is, therefore, a new drug under section 201(P) of the Act (21 U.S.C. § 321 (P)). Under section 505(a) of the Act (21 U.S.C. § 355(a)), a new drug may not be introduced or delivered for introduction into interstate commerce unless it is the subject of an FDA-approved application. The marketing of Listerine Total Anticavity Mouthwash without an FDA-approved application violates this provision of the Act

In addition, the front panel of your product states the product name: "Listerine Total Care Anticavity Mouthwash." The

violative claims described in the above paragraphs, combined with the appearance of the "Total Care" name, suggests that the product is comprehensive in function, and will provide benefits, including antigingivitis and antiplaque benefits. We are not aware of any support for the antiplaque/antigingivitis claims or other statements suggesting that the product is comprehensive in function, providing benefits beyond those related to prevention of cavities. Thus, the product's labeling claim that it will provide all of the benefits listed, is misleading and accordingly makes it misbranded within the meaning of section 502(a) of the Act. (21 U.S.C. §352(a)).

The violations cited in this letter are not an all-inclusive list of deficiencies. You are responsible for investigating and determining the causes of these violations and for preventing their recurrence and the occurrence of other violations. You are to assure that your firm complies with all requirements of federal law and FDA regulations.

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.

We note additionally that your principal display panel (PDP) describes your product as "Sodium Fluoride and Acidulated Phosphate Topical Solution." The Drug Facts panel lists the sole active ingredient as "Sodium fluoride 0.0221% (0.01% fluoride ion)." These representations are inconsistent. Based on the information in your Drug Facts panel, it appears that the PDP should refer to either "Sodium Fluoride Acidulated Phosphate Solution" or just "Sodium Fluoride Solution." The Sodium fluoride listed in the drug facts panel should be listed at 0.02%; not 0.0221 %.

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 addressed to Robert J. Maffei, Compliance Officer, at the above address.

Sincerely,

/s/

DIANA AMADOR-TORO
District Director
New Jersey District Office

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