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CITIZEN PETITION

This citizen petition is submitted under 21 C.F.R. §§ 10.30 and 10.35(b) to request the Commissioner of Food and Drugs (hereinafter, the "Commissioner") to amend its approval of the new drug application ("NDA") for a nonprescription form of Prilosec (omeprazole magnesium) (hereinafter referred to as "Prilsec OTC") to require that Prilosec OTC be sold under a different brand name in order to reduce otherwise inevitable consumer confusion and decrease the potential for misuse of Prilosec OTC.

The basis of this petition, as discussed in more detail below, is that Prilosec OTC has been approved solely for the treatment of frequent heartburn occurring two or more days a week, while the prescription version of Prilosec® is used for treatment of gastro-esophageal reflux disease ("GERD"), including the treatment of heartburn and other systems associated with

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GERD, as well as a host of other gastro-intestinal diseases. If these very different products are allowed to be marketed and sold under the same brand name, consumers will be dangerously confused.

BACKGROUND

On June 20, 2003, the United States Food and Drug Administration (the "FDA") approved the NDA for a delayed-release 20mg tablet of omeprazole magnesium that will be available to consumers under the name of Prilosec OTC, without a prescription, for the treatment of frequent heartburn occurring two or more days a week. However, a 20mg omeprazole delayed release capsule (approved by the FDA on September 14, 1989) remains available with a physician's prescription. At the same time a 40mg delayed release capsule (approved by the FDA on January 15, 1998), and a 10mg omeprazole delayed release capsule (approved by the FDA on October 5, 1995) also remain available as prescription drugs for the treatment of GERD, including the treatment of frequent heartburn and other symptoms associated with GERD as well as other serious medical conditions.

A. Action Requested

This petition requests that the Commissioner amend its approval of the NDA for Prilosec OTC to require that the product be sold under some name other than Prilosec® in order to reduce the risk of consumer confusion and decrease the potential for misuse. On November 20, 2002, Andrx Pharmaceutical Corporation ("Andrx") submitted a citizen petition to the FDA advocating the denial of approval of an over-the-counter omeprazole product. Among the requests made by Andrx was that even if Prilosec OTC is approved by the FDA, it should be renamed to reduce consumer confusion. The FDA, perhaps by oversight, did not fully address this issue in its

memorandum dated June 20, 2003, responding to Andrx's citizen petition. Even though the FDA placed the product through its look alike sound alike name evaluation, the FDA did not address the issue of patient misuse. This consumer safety issue is too important to be left unaddressed.

B. Statement of Grounds

Using the trade name "Prilosec" in the sales and marketing of Prilosec OTC carries the connotation that Prilosec OTC is the same product as prescription Prilosec®. The implication that the products are the same is inaccurate, misleading, and dangerous as consumers could mistakenly self-diagnose and self-treat conditions that should otherwise be diagnosed and treated only by a licensed medical professional. Additionally, this potential for negative patient sequelae may manifest itself via an increase in disease-state morbidity and an increase in related healthcare costs.

AstraZeneca has heavily promoted Prilosec® in print, television, radio, and internet DTC (direct to consumer) advertisements. AstraZeneca's consumer branding of Prilosec® as the "Purple Pill" has been one of the most extensive advertising campaigns in pharmaceutical history. Such advertisements were created and put forth to educate consumers about the use of Prilosec® (the "Purple Pill") for the treatment of GERD. All related ad content, to include the "fair balance" disclosures required by the FDA for Prilosec OTC, was based upon the approved labeling for Prilosec®. This is an important distinction as the labeling for Prilosec® and "Prilosec" OTC are dramatically different.

A study published in November 2001 by the Kaiser Family Foundation (*Understanding the Effects of Direct-to-Consumer Drug Advertising* - available at www.kff.org/marketplace),

found that 84% of study participants found that pharmaceutical DTC ads they had seen did a "good" or "excellent" job of telling them about the condition that the advertised medication is designed to treat. Additionally, 72% of participants stated that the DTC ads they had seen did a "good" or "excellent" job identifying the medicine's potential benefits. The results of this survey demonstrate that DTC advertising is effective in influencing consumer choice regarding the selection and use of prescription medications.

In the case of Prilosec OTC, AstraZeneca's massive DTC advertising campaign has surely conditioned consumers at large. The preponderance of Prilosec DTC "Purple Pill" advertising has forever limited the name "Prilosec" and the information presented in the Prilosec DTC ads; namely the treatment of GERD (as well as other information regarding Prilosec that was presented in the DTC ads). Re-use of the name "Prilosec" in the over-the-counter product will cause consumers to associate and apply their prior learnings regarding Prilosec® (derived from a barrage of Prilosec DTC ads) to the use of Prilosec OTC. The result will likely be the inappropriate use of Prilosec OTC to treat conditions such as GERD, conditions for which Prilosec OTC has not been approved, and which need to be evaluated, diagnosed and treated by a physician. Inappropriate self-medication of these conditions with an OTC product may result in a worsening of the consumer's condition, or the development of other serious gastrointestinal diseases such as erosive esophigitis and its potential sequalae esophageal cancer[1].

The branding of Nexium® (esomeprazole magnesium) in AstraZeneca's DTC advertisements as the "new Purple Pill" further elevates the potential for consumer confusion and

[1] Shaheen, N and Ransohoff, D Gastroesophageal Reflux, Barrett Esophagus, and Esophageal Cancer: Scientific Review; Journal of the American Medical Association 287 (15) April 2002 pp 1972-1981.

misuse of Prilosec OTC. Nexium®, also identified as the "Purple Pill", is currently heavily promoted to treat GERD with the tag line "relieve the heartburn heal the damage" (visit www.purplepill.com for an example of the current campaign). Once again, the label and approved uses of Nexium® and Prilosec OTC are drastically different. The redundant use of the term "Purple Pill" to promote both Prilosec® and Nexium® creates another layer of consumer confusion, in this case, drawing an inappropriate connection between the advertised claims regarding the use of Nexium® and applying them to Prilosec OTC.

Although other drugs have been approved for marketing as over-the-counter and prescription products under the same brand name, those approvals occurred before DTC advertising was as widely used as it is today. It was not until 1997 when the FDA revised regulations regarding the advertising of pharmaceutical products that DTC advertising began to proliferate. The approval of Prilosec OTC signifies the first transition of a new therapeutic class to over-the-counter status since 1997, in which the OTC product is approved at different strengths and limited indications compared to the prescription product[2]. Therapeutic classes that transitioned to over-the-counter status prior to 1997, (for example, H2 blockers such as Tagamet and Zantac – both approved at one-half (½) the strength of the prescription products-; NSAIDs such as Motrin and Orudis – both approved at reduced strengths to the prescription products) have re-used the same trade name in the over-the-counter product branding as was used in the prescription product, but mass media pharmaceutical DTC advertising did not exist at the time.

[2] When the FDA approved the switch of Claritin to OTC status in 2002, the concerns that are discussed above regarding Prilosec OTC switch did not exist since the product was approved for OTC sale at the same strength, dosage forms, and use as the prescription product.

Therefore, the dangers of consumer bias and confusion based upon DTC advertising of Prilosec® did not exist when these products entered the over-the-counter market.

In addition, the FDA has recognized that drugs whose name look alike in handwriting or sound alike can dangerously increase the risk of confusion. The FDA's Medication Error Subcommittee has been tracking this type of medication error since June of 1992, and has requested several manufacturers to change the names of certain drugs. For example, at the FDA's request, Levoxine's manufacturer changed the name to Levoxyl®. Also, at the FDA's request, Prilosec's name was changed in 1990 from Losec, which was being confused with diuretic Lasix (furosemide). Using the same brand name for both the prescription and over-the-counter omeprazole products further elevates the risk of medication error, because the brand name for both products not only looks alike and sounds alike, but is literally the same.

There is sufficient risk of consumer confusion and potential for patient misuse to warrant an investigation as to the appropriateness of utilizing the "Prilosec" name in the trade packaging and marketing of Prilosec OTC. To the extent that consumers will be misled by the common use of the name "Prilosec", it is in the best interest of public health and safety to require Prilosec OTC to be marketed under a name that does not include the word "Prilosec" as part of the name.

C. Environmental Impact

The actions requested herein are subject to categorical exclusion under 21 C.F.R. § 25.31.

D. Economic Impact

An economic impact statement will be submitted at the request of the Commissioner.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,

Aug 12, 2003
Date

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