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Dockets Management Branch
Food and Drug Administration
HFA-305
5630 Fishers Lane
Room 1061
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In Quadruplicate

AMENDMENT TO CITIZEN PETITION 00P-1245 / CP1

This amendment is submitted in quadruplicate to Docket No. 00P-1245 / CP1. The purpose of this amendment is to address additional issues related to the Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients: Final Rule and the requirements set forth in 21 CFR 314.55. As described, these regulations require information to assess the safety and effectiveness of the drug product for the claimed indications in all relevant subpopulations, and to support dosing and administration in each subpopulation for which the drug is safe and effective. Alternatively, the FDA may grant a full or partial waiver of the requirements for pediatric studies on its own initiative, or at the request of the applicant [21 CFR 314.55(c)(1)].

The Update of the List of Approved Drugs for Which Additional Pediatric Information May Produce Health Benefits in the Pediatric Population dated May 19, 2000, lists erosive esophagitis as the indication for Nizatidine prescription strengths for which additional information is being sought. The approved indication for over-the-counter Nizatidine, prevention of heart burn, acid indigestion, and sour stomach brought on by consuming food and beverages, is not contained on this list. Additionally, a number of other products (e.g., Mylanta, Maalox, etc. that are the subject of OTC monographs) are currently available to the pediatric population, which provides an alternative for the proposed OTC indication. Thus, there would be no benefit for the Agency to consider this product for inclusion on the list. These alternative over-the-counter products are available in a variety of dosage forms that provide convenient options for administration depending on the needs of the individual. Because the approved indication for over-the-counter strengths of Nizatidine has not been identified as an indication for which the Agency is seeking additional pediatric information, the

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Agency may on its own initiative decide to waive the requirement for pediatric studies. Therefore, a determination that pediatric study requirements may be waived is a reasonable decision by the Agency for this specific product.

The Agency may also waive the study requirements for pediatric age groups if it concludes:

1. The product does not represent a meaningful therapeutic benefit over existing treatments, and the product was not likely to be used in a substantial number of pediatric patients.
2. The necessary studies are impossible or highly impractical, because, for example, the number of such patients is so small or geographically dispersed.
3. There is evidence strongly suggesting that the product would be ineffective or unsafe in some or all pediatric populations.

There are currently many drug products available as over-the-counter remedies for heartburn, acid indigestion and sour stomach. Such products are available in liquid, tablet and chewable tablet dosage forms. The availability of multiple dosage forms for already marketed products offers a variety of options. The availability of a capsule dosage form of Nizatidine would not likely promote the use of the product in pediatric patients in age groups not already covered by the approved labeling

Therefore, the petitioner believes that the waiver request is in accord with the concepts of the regulations cited above. Based on the information provided, the petitioner requests that the Commissioner find that the change from a tablet to a capsule for Nizatidine 75 mg raises no questions of safety or effectiveness and the petition be approved.

Respectfully submitted,

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cc: G. Davis (OGD), L. Lachman, Ph.D., R. Pollock

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