October 31, 2006

Taro Pharmaceuticals U.S.A., Inc.

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane
Room 1061 (HFA-305)
Rockville, Maryland 20852

CITIZEN PETITION

The undersigned submits this petition pursuant to section 505 (j) (2) (c) of the Federal Food, Drug and Cosmetic Act and 21 CFR Parts 314.55 (d) (2) and 10.30 of the Food and Drug Administration's regulations, to request the Commissioner of food and Drugs to make a determination of ANDA suitability for PHENERGAN® Promethazine Hydrochloride Suppositories USP, 12.5 mg and 25 mg, were voluntarily withdrawn from sale for reasons other than safely and effectiveness.

A. Action Requested

The petitioner requests the Commissioner of the Food and Drug Administration for a change to a listed drug to allow an Abbreviated New Drug Application for Promethazine Hydrochloride Suppositories USP, 12.5 mg and 25 mg, manufactured by Wyeth-Ayerst, and were voluntarily withdrawn from sale for reasons other than safety and effectiveness.

B. Statement of Grounds

The reference products, PHENERGAN®, Promethazine Hydrochloride Suppositories USP 12.5 mg and 25 mg, have been discontinued by Wyeth Pharmaceuticals, Inc., and are currently listed in the Approved Drug Products with Equivalence Evaluation (the "Orange Book") under "DISCONTINUED DRUG PRODUCT LIST."

The undersigned has no information suggesting that both 12.5 mg and 25 mg strengths of PHENERGAN® Promethazine Hydrochloride Suppositories were withdrawn for reasons

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of safety and effectiveness, and both strengths remain approved and distributed by various companies [see Exhibit 1].

C. Environmental Impact

The undersigned hereby requests a categorical exclusion under 21 CFR 25.24 (c) (1). The proposed drug product will not be administered at higher dosage levels, for longer duration, or for different indications than for the listed product.

D. Economic Impact

This information will be submitted on request of the Commissioner.

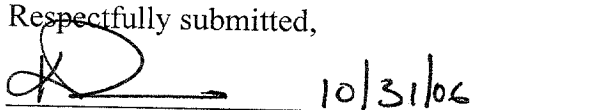
E. Advantages

The proposed Promethazine hydrochloride Suppositories USP, 12.5 mg and 25 mg will provide the physicians a greater flexibility in prescribing the drug in a lower cost to the patients.

F. Certification

The undersigned certifies, that to the best knowledge and belief of the undersigned, this petition includes all information and view 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,



10/31/06

Kalpana Rao
GVP, Regulatory Affairs (Global)
Taro Pharmaceuticals U.S.A., Inc.