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Division of Dockets Management
Food and Drug Administration (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Sir or Madam:

The undersigned submits this petition in quadruplicate pursuant to 21 CFR 10.30 and in accordance with the regulations at 21 CFR 314.161, requesting the Commissioner of the Food and Drug Administration to provide a determination whether a listed drug has been withdrawn for safety or effectiveness reasons as outlined below.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration determine whether Vioxx Tablets, manufactured by Merck has been voluntarily withdrawn or withheld from sale for safety or efficacy reasons.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products that are eligible for submission as abbreviated new drug applications (ANDAs). The List, referred to as the Orange Book, contains all FDA-approved drug products; Vioxx Tablets were approved by the FDA on May 20, 1999 (12.5mg and 25 mg) and February 25, 2000 (50 mg) and were, upon approval, considered to be "listed drug products" in the Orange Book. These products currently appear in the discontinued section of the Orange Book.

Under FDA regulations, drugs are withdrawn from the list if the Agency withdraws or suspends approval of the drug product's application for reasons of safety or effectiveness, or if the FDA determines that the listed drug was withdrawn or withheld from sale for reasons of safety or effectiveness (21 CFR 314.162). The regulations also provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (21 CFR 314.161 (a) (1)).

2005-P-0079

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Merck suspended marketing of Vioxx on September 30, 2004 for potential reasons of safety. On information and belief that FDA will or has restored Merck's ability to market Vioxx, Teva requests that FDA determine that Vioxx is again a marketable product no longer considered to be withdrawn for reasons of safety of efficacy.

C. Environmental Impact

A claim for categorical exclusion of the requirement for submission of an environmental assessment is made pursuant to 21 CFR 25.31.

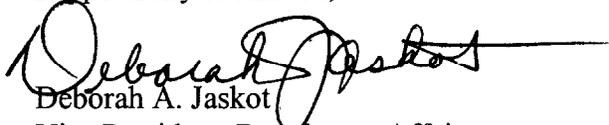
D. Economic Impact

Pursuant to 21 CFR 10.30 (b), economic impact information is to be submitted only when requested by the Commissioner. This information will promptly be submitted, if so requested.

E. Certification

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

Respectfully submitted,



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Cc: Martin Shimer (Office of Generic Drugs)