Citizen Petition

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The undersigned submits this petition, in quadruplicate, under section 21 U.S.C. § 355 (j) (2) (c) and 21 CFR §10.20 and § 10.30, and 21 CFR 314.93, to request the Commissioner of Food and Drugs Administration to accept an Abbreviated New Drug Application (ANDA) for the Petitioner's Diphenhydramine Hydrochloride Injection USP, 50 mg /mL (SDV and MDV).

A. Action Requested

This petition requests the Commissioner of Food and Drugs to accept ANDAs for Diphenhydramine Hydrochloride Injection USP, 50 mg /mL (SDV and MDV). It is to be noted that our proposed formulation of Diphenhydramine Hydrochloride Injection USP, 50 mg/mL is equivalent to McNeil Cons discontinued Benadryl(1) (NDA No. N006146 and N009486, approved prior to Jan 1, 1982). McNeil Cons discontinued Benadryl (Diphenhydramine Hydrochloride Injection USP), and FDA has determined that this presentation of Benadryl Injection was not withdrawn from sale for reasons of safety or effectiveness, copy of federal register is presented as Exhibit - I.

B. Statement of Grounds

McNeil Cons, first obtained approval of a New Drug Application (NDA) for Benadryl (NDA N006146). Prior to Jan 1, 1982, Hikma Maple obtained approval of Diphenhydramine Hydrochloride Injection USP, 50 mg /mL (ANDA A080817). The Hikma Maple's formulation of Diphenhydramine Hydrochloride Injection USP, 50 mg /mL, is equivalent in use, dosage, and route of administration to the McNeil Cons discontinued Benadryl (Diphenhydramine Hydrochloride Injection USP). The FDA approved label information for the Hikma Maple's formulation of Diphenhydramine Hydrochloride Injection USP is provided as Exhibit – II and discontinued label information for the McNeil Cons discontinued Benadryl (Diphenhydramine Hydrochloride Injection USP) is provided as Exhibit – III. The FDA has moved McNeil Cons discontinued Benadryl (Diphenhydramine Hydrochloride Injection USP), to the discontinued section of the "Orange Book" (Exhibit - IV). Further, the Agency has also made the determination that the Benadryl formulation was not withdrawn from sale, for reasons relating to safety or effectiveness. This determination was published in the Federal Register on March 19, 2012 and allows the Agency to review and approve ANDAs for the formulation referring to the McNeil Cons discontinued listed drug product, as per 21 CFR 314.93. It is known from the Code of Federal Regulations that when an ANDA makes reference to a discontinued label of a drug, FDA may still approve the ANDA upon determination that the formulation was not withdrawn for reasons of safety or effectiveness (21 U.S.C. Section 355(j)(6) and 21 CFR §§ 314.122 and 314.161).

C. Environment Impact

Action on an ANDA is categorically excluded from the requirements of an environmental assessment or impact statement under 21 CFR 25.31 (a).

*(1) **Benadryl** (diphenhydramine), a brand name of antihistamine (allergy medicine) was marketed over-thecounter*

by Johnson & Johnson subsidiary McNeil Consumer Healthcare. Prior to 2007, Benadryl was marketed by Pfizer Consumer Healthcare.

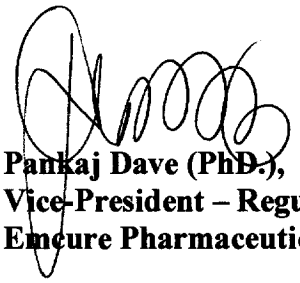
D. Economic Impact

Information regarding economic impact will be made upon request.

E. Certification

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

Sincerely,



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