2013 JUN -6 P 12:59

May 31, 2013

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

As directed by the FDA, Elite Laboratories, Inc. (Elite) submits this petition pursuant to 21 CFR 314.122 requesting that the FDA make a determination that (a) it is suitable to use as a Reference Listed Drug (RLD) a currently approved and marketed ANDA product due to the fact that the currently listed Orange Book RLD is unavailable in the marketplace, and (b) that this currently approved and marketed ANDA product is suitable to use as a RLD for an equivalent active ingredient comprised of a different salt.

ACTION REQUESTED

Elite requests the FDA's determination that: (a) the approved and marketed product reflected in ANDA 078648 (dexbrompheniramine maleate, 6mg/ pseudoephedrine sulfate 120 mg, extended release, Avanthi, Inc) is suitable to use as a Reference Listed Drug (RLD) as the current Orange Book RLD (N013483, Drixoral, dexbrompheniramine maleate 6mg/pseudoephedrine sulfate, 120 mg, extended release, Schering Plough) is not available in the marketplace, and (b) that this currently approved and marketed ANDA product is suitable to use as a RLD for a product containing an equivalent amount of an active ingredient which is comprised of a different salt.

STATEMENT OF GROUNDS

The currently listed Orange Book Reference Listed Drug (RLD) is Drixoral (N013483), approved September 13, 1982. This product has been unavailable in the marketplace since approximately June, 2008. It is Elite's understanding that Schering-Plough (Pfizer), the innovator and previous marketer, ceased making this product in 2008 due to difficulty in its manufacture and its correspondingly low sales volume. Drixoral had been previously marketed since 1982 and ceasing it manufacture does not appear to have been related to any safety issue. As noted, it remains listed as the RLD. Avanthi Inc. was granted approval of a generic formulation of Drixoral (ANDA 078648) on February 27, 2013. This application used the previously available Drixoral product as it RLD. Absent the availability of Drixoral in the marketplace, Elite requests that use of the currently available ANDA product be allowed as a RLD.

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Additionally, Drixoral and the recently approved and marketed ANDA product contain active pseudoephedrine as the sulfate salt. The finalized FDA OTC monograph for Cough/Cold products lists pseudoephedrine sulfate and pseudoephedrine HCl (in identical amounts of pseudoephedrine) as being equivalent, both as a nasal decongestant and bronchodilator (341.20(a)(2), 341.20(a)(3), 310.545(a)(6)(iv). On the basis of this stated equivalency, Elite requests FDA's determination that the currently approved and marketed ANDA product (ANDA 078648) is suitable as a RLD for a formulation containing dexbrompheniramine maleate and pseudoephedrine hydrochloride.

ENVIROMENTAL IMPACT

Elite believes that this petition is subject to categorical exclusion under CFR 25.31. The development and subsequent marketing which would result from affirmation of the above requested determinations should have little to no impact on the total dexbrompheniramine and/or pseudoephedrine market and hence is not expected to increase the use of either active ingredient. Use of this product may replace other currently marketed products but should not increase the overall use of the drug entities.

ECONOMIC IMPACT

Increased competition in this segment of the antihistamine/decongestant marketplace should not only provide more patient and physician alternatives but moderate cost. At this time only one product containing these ingredients appears in the marketplace.

CERTIFICATION

The undersigned certifies that, to the best of his knowledge and belief, 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 maybe unfavorable to the petition.

Jerry Treppel
(Signature)

Jerry Treppel
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