Elite Laboratories Files Citizen Petition With The Fda On Brompheniramine Maleate And Pseudoephedrine Hcl Extended Release

Release: 6/10/2013 12:00:00 PM

Northvale, New Jersey, Monday, June 10, 2013: Elite Laboratories, a wholly owned subsidiary of Elite Pharmaceuticals, Inc. (collectively ""Elite" or the "Company") (OTCBB: ELTP) today announced that the Company submitted a Citizen Petition to the U.S. Food and Drug Administration (the "FDA") requesting that the FDA make a determination that (a) it is suitable to use the currently approved and marketed ANDA product (ANDA 078648, generic to Drixoral brand) as the Reference Listed Drug ("RLD") since the current RLD Drixoral brand is no longer available 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 difference salt.

The filing of the Citizen Petition represents another step forward in Elite's continuing efforts to reintroduce its extended release brompheniramine maleate and pseudoephedrine hydrochloride to the marketplace.

Citizen petitions are filed to ask that the FDA take, or refrain from taking, a particular action. Any person may file a citizen petition, and any person may comment on a petition that has been filed. Petitions are governed by and must comply with FDA regulations, specifically 21 C.F.R. § 10.30, as well as the Federal Food, Drug, and Cosmetic Act, specifically 21 U.S.C. § 355(q) when applicable.

Elite cannot predict when or if the FDA will respond to, or otherwise take any action with respect to, the Citizen Petition.

About Elite Pharmaceuticals, Inc.
Elite Pharmaceuticals, Inc. develops oral sustained and controlled release products. Elite's strategy includes assisting partner companies in the life cycle management of products to improve off-patent drug products and developing generic versions of controlled release drug products with high barriers to entry. Elite has five commercial products currently being sold, an additional product approved and soon to be launched, and one additional product under review pending approval by the FDA. Elite's lead pipeline products include abuse resistant opioids utilizing the Company's patented proprietary technology, and a once-daily opioid. They are sustained release oral formulations of opioids for the treatment of chronic pain, which address two of the limitations of existing oral opioids: the provision of consistent relief of baseline pain levels and deterrence of potential abuse. Elite also provides contract manufacturing for Actavis and Ascend Laboratories (previously a subsidiary of ThePharmaNetwork and now a subsidiary of Alkem Laboratories Ltd.) and has partnered with Mikah Pharma to develop a new product, with Hi-Tech Pharmacal to develop an intermediate for a generic product, and a Hong Kong based company to develop a branded product for the United States market and its territories. Elite operates a GMP and DEA registered facility for research, development, and manufacturing located in Northvale, NJ.

This news release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Including those related to the effects, if any, on future results, performance or other expectations that may have some correlation to the subject matter of this press release, readers are cautioned that such forward-looking statements involve risks and uncertainties including, without limitation, delays, uncertainties, inability to obtain necessary ingredients and other factors not under the control of Elite, which may cause actual results, performance or achievements of Elite to be materially different from the results, performance or other expectations that may be implied by these forward-looking statements. These risks and other factors, including, without limitation, the Company's ability to obtain sufficient funding under the LPC Agreement or from other sources, the timing or results of pending and future clinical trials, regulatory reviews and approvals by the Food and Drug Administration and other regulatory authorities, intellectual property protections and defenses, and the Company's ability to operate as a going concern, are discussed in Elite's filings with the Securities and Exchange Commission, including its reports on forms 10-K, 10-Q and 8-K. Elite undertakes no obligation to update any forward-looking statements.