



NDA 21-604/S-003

Taro Pharmaceuticals, USA, Inc.
Attention: Kalpana Rao
Vice President, Regulatory Affairs (Global)
3 Skyline Drive
Hawthorne, NY 10532

Dear Ms. Rao:

Please refer to your supplemental new drug application dated August 23, 2005, received August 30, 2005, submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Children's ElixSure IB (100 mg/5 mL ibuprofen) suspension.

We acknowledge receipt of your submission dated December 8, 2005.

This supplemental new drug application provides for revisions to the Drug Facts label and Principal Display Panel for the Children's Elixsure 4- and 1-ounce package sizes in response to the June 14 and July 15, 2005 supplemental labeling request letters.

We have completed our review of this application, as amended. This application is approved for the Children's Elixsure, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on December 8, 2005 for the 4- and 1-ounce package size carton and immediate container labels and for the package insert labeling for the 1-ounce package size.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Neel Patel, Regulatory Project Manager, at (301) 796-0970.

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, MD
Acting Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Andrea Segal
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