DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-604

Taro Pharmaceuticals Inc.
Attention: Kalpana Rao
Vice President, Regulatory Affairs
Five Skyline Drive
Hawthorne, NY 10532

Dear Ms. Rao:

Please refer to your new drug application (NDA) dated December 30, 2002, received December 31, 2002, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Children's ElixSure™ IB (ibuprofen) Oral Suspension, 100 mg/5 mL.

We acknowledge receipt of your submissions dated November 18, December 18 and 19, 2003, and January 6, 2004.

The November 18, 2003 submission constituted a complete response to our October 31, 2003 action letter.

This new drug application provides for the use of Children's ElixSure™ IB (ibuprofen) Oral Suspension, 100 mg/5 mL for the relief of minor aches and pains due to the common cold, flu, sore throat, headache, toothache and reduction of fever in children.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to submitted labeling (immediate container and carton labels submitted December 18 and 19, 2003), and must be in the "Drug Facts" format (21 CFR 201.66). Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-604**." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for this application.

In addition, we request that you submit two copies of the introductory promotional materials you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Please send one copy, along with labeling, to each of the Divisions signing below.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

Oversight of this application is being transferred to the Division of Over-the-Counter Drug Products.

If you have any questions, please call Walter Ellenberg, PhD, Regulatory Health Project Manager at (301) 827-2222.

Sincerely,

{See appended electronic signature page}

Charles Ganley, MD
Director
Division of Over-the-Counter Drug Products, HFD-560
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Brian E. Harvey, MD, PhD
Acting Director
Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
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/

Charles Ganley
1/7/04 03:13:42 PM

Brian Harvey
1/7/04 03:47:13 PM