DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21604/S-004

SUPPLEMENT APPROVAL

Moberg Pharma North America, LLC
c/o Innovative Science Solutions, LLC
Attention: Steven W. Weisman, Ph.D.
67 Park Place East, 6th Floor
Morristown, NJ 07960

Dear Dr. Weisman:

Please refer to your Supplemental New Drug Application (sNDA) dated October 9, 2013, received October 10, 2013, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Children's Elixsure IB (ibuprofen) oral suspension, 100 mg/5 mL.

We acknowledge receipt of your amendments dated November 5 and 26, 2013 and January 10, 2014.

This "Prior Approval" sNDA provides for the requested labeling changes described in our July 1, 2013 Prior Approval Supplement Request letter. Specifically, you were asked to revert to the most recently approved labeling found in sNDA S-003 and include changes described in previous FDA correspondences.

We have 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 and with the minor editorial revision listed below:

- Under the Directions Heading of the Consumer Information Leaflet, add a space in between the words "times" and "a". This revision can be done at the time of final printed labeling.

LABELING

Submit final printed labeling (FPL), with the revision listed above, as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the labels listed below and must be in the "Drug Facts" format (21 CFR 201.66), where applicable:

Submitted Labeling	Date Submitted
4-fluid-ounce outer carton	01/10/2014
4-fluid-ounce immediate container	11/26/2013

12 x 1-fluid-ounce sample-bottle display carton	01/10/2014
1-fluid-ounce professional sample immediate container	01/10/2014
1-fluid-ounce professional sample consumer information leaflet	01/10/2014

The FPL should be submitted electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 21604/S-004**." Approval of this submission by FDA is not required before the labeling is used.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

REPORTING REQUIREMENTS

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

If you have any questions, call Jade Pham, Regulatory Project Manager, at (301) 796-7031.

Sincerely,

{See appended electronic signature page}

Theresa Michele, M.D.
Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):
Carton and Container Labeling

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

/s/

THERESA M MICHELE
03/31/2014