



NDA 21604/S-005

SUPPLEMENT APPROVAL

Innovative Science Solutions, LLC on behalf of
Moberg Pharma North America, LLC
Attention: U.S. Agent: Steven M. Weisman, PhD
67 Park Place East
Morristown, NJ 07960

Dear Dr. Weisman:

Please refer to your Supplemental New Drug Application (sNDA) dated September 14, 2016, received September 15, 2016, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Children’s ElixSure IB (ibuprofen 100 mg/5 mL) oral suspension.

This “Changes Being Effected” supplemental new drug application provides for the addition of the “Heart attack and stroke warning” in accordance with the “Changes Being Effected” (CBE-0) Request Letter from the Agency dated August 18, 2016.

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.

LABELING

Submit final printed labeling as soon as they are available, but no more than 30 days after they are printed. The final printed labeling must be identical to the Children’s ElixSure IB oral suspension labels listed in the table below and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

Submitted Labeling	Date Submitted
1 fl. oz. professional sample immediate container	January 11, 2017
12 x1 fl. oz. sample- bottle display carton	November 8, 2016 (paper document); December 1, 2016 (via email as a pdf)
1 fl. oz. professional sample consumer information leaflet (CIL)	November 8, 2016 (paper document); December 1, 2016 (via email as a pdf)
4 fl. oz. immediate container	January 11, 2017
4 fl. oz. outer carton	January 12, 2017

The final printed labeling 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-005.**” 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 CAPT Janice Adams-King, Safety Project Manager, at (301) 796-3713.

Sincerely,

{See appended electronic signature page}

Valerie Pratt, MD
Deputy Director for Safety
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURES:
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/

VALERIE S PRATT
03/15/2017