NDA 019774/S-053

SUPPLEMENT APPROVAL

Ferring Pharmaceuticals Inc.
Attention: Kevin Wyckoff, MS
Director, Regulatory Affairs
100 Interpace Parkway
Parsippany, NJ 07054

Dear Mr. Wyckoff:

Please refer to your supplemental new drug application (sNDA) dated December 19, 2018, received December 19, 2018, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zomacton (somatropin) for injection.

This “Changes Being Effected” supplemental new drug application provides for addition of the text "For use with needle-free ZOMA-Jet® 10 only" in the carton labeling for the 10 mg needle free drug product containing the vial adapter.

APPROVAL & LABELING

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

CARTON AND CONTAINER LABELING

We acknowledge your December 19, 2018, submission containing final printed carton and container labeling.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

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 Sejal Kiani, Regulatory Project Manager, at (301) 796-6445.

Sincerely,

{See appended electronic signature page}

Lisa B. Yanoff, M.D.
Director (Acting)
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE:

- Carton Labeling

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

LISA B YANOFF
03/13/2020 03:48:34 PM