NDA 209022/S-010
NDA 209022/S-011

SUPPLEMENT APPROVAL

OptiNose US, Inc.
1020 Stony Hill Road, Suite 300
Yardley, PA 19067

Attention: Amanda Martin, PhD
Senior Director, Regulatory Affairs

Dear Dr. Martin:

Please refer to your supplemental new drug applications (sNDA) dated October 29, 2020, and January 25, 2021, received October 29, 2020, and January 25, 2021, and your amendment, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Xhance (fluticasone propionate) Nasal Spray.

"Changes Being Effected in 30 days" supplemental new drug application (NDA 209022/S-010) provides for the addition of a new secondary packaging component to the bottom of the glass vial ('Base') to provide additional protection against damage to the glass during use, replacing the approved secondary packaging (Tray/Lid/Carton) with a new side opening carton, and updating the corresponding sections of the prescribing information, the patient prescribing information, and the Instructions for Use.

"Changes Being Effected in 30 days" supplemental new drug application (NDA 209022/S-011) provides for the update of the labeling (package insert, carton/container labels) to include a statement regarding sodium hydroxide and hydrochloric acid as pH adjusters per the FDA CBE-30 Supplement Request Letter dated December 29, 2020.

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at

FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, Patient Package Insert, Instructions for Use), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry SPL Standard for Content of Labeling Technical Qs and As.

The SPL will be accessible from publicly available labeling repositories.
Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labeling for approved NDA 209022/S-011**." Approval of this submission by FDA is not required before the labeling is used.

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, contact Nina Ton, Senior Regulatory Project Manager, at (301) 796-1648.

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

Sincerely,

{See appended electronic signature page}

Sally Seymour, MD
Director
Division of Pulmonology, Allergy, and Critical Care
Office of Immunology and Inflammation
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert
  - Instructions for Use
- Carton and Container 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/

BANU A KARIMI SHAH
04/29/2021 06:38:26 PM
signing with the delegated authority of Dr. Sally Seymour, Director, DPACC