Dear Ms. Gallagher:

Please refer to your new drug application (NDA) dated and received on May 17, 2021, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nasonex 24HR Allergy (mometasone furoate) nasal spray, 50 mcg/spray, metered.

This new drug application provides for the use of Nasonex 24HR Allergy for the following indication(s):

Temporarily relieves these symptoms of hay fever or other upper respiratory allergies:
- Nasal congestion
- Runny nose
- Sneezing
- Itchy nose

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 (FPL), as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the enclosed labeling described in the table below and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.
### Submitted Draft Labeling

<table>
<thead>
<tr>
<th>Submitted Draft Labeling</th>
<th>Date Submitted</th>
</tr>
</thead>
<tbody>
<tr>
<td>120 spray count blister card (secondary packaging)</td>
<td>2/7/2022</td>
</tr>
<tr>
<td>120 spray count container label</td>
<td>2/7/2022</td>
</tr>
<tr>
<td>60 spray count blister card (secondary packaging)</td>
<td>2/7/2022</td>
</tr>
<tr>
<td>60 spray count container label</td>
<td>2/7/2022</td>
</tr>
<tr>
<td>30 spray count blister card (secondary packaging)</td>
<td>2/7/2022</td>
</tr>
<tr>
<td>30 spray count container label</td>
<td>2/7/2022</td>
</tr>
<tr>
<td>Consumer Information Leaflet (Package Insert for all Nasonex 24HR Allergy SKUs)</td>
<td>2/7/2022</td>
</tr>
</tbody>
</table>

The FPL should be submitted 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 “**Final Printed Labeling for approved NDA 215712.**” Approval of this submission by FDA is not required before the labeling is used.

### Additional Comments

We have approved package sizes for this product amid concerns that consumers follow instructions that limit duration of use of over-the-counter nasal corticosteroids to no longer than 2 months a year in children. The “Directions” section of the Drug Facts labeling for the product states “Talk to your child’s doctor if your child needs to use the spray for longer than two months a year.”

Research has shown that increased package sizing of products leads to increased usage among consumers. Conversely, limiting pack sizes of medication has been shown to reduce episodes of overconsumption by limiting the immediate availability of the drug to the consumer.

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1. We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database [https://www.fda.gov/RegulatoryInformation/Guidances/default.htm](https://www.fda.gov/RegulatoryInformation/Guidances/default.htm).

U.S. Food and Drug Administration
Silver Spring, MD 20993
[www.fda.gov](http://www.fda.gov)
If you are interested in marketing a package configuration that would extend use beyond 2 months in children, we advise you to request a meeting with us to discuss the safety and efficacy implications, consumer use patterns, and data needed to support a prior approval supplement submission.

**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 FDA.gov. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs & As*. 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.

**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 Phong Pham, PharmD, MBA, Regulatory Project Manager, at (301) 837-7656.

Sincerely,

{See appended electronic signature page}
ENCLOSURE(S):
• 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/

NUSHIN F TODD
03/17/2022 11:49:28 AM