

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

022051Orig1s017

Trade Name: Flonase Sensimist Allergy Relief

Generic or Proper Name: Fluticasone Furoate Nasal Spray, 27.5 mcg per spray

Sponsor: GlaxoSmithKline Consumer Healthcare

Approval Date: August 23, 2017

Indication: Temporarily relieves these symptoms of hay fever or other upper respiratory allergies: nasal congestion, runny nose, sneezing, itchy nose, itchy watery eyes.

CENTER FOR DRUG EVALUATION AND RESEARCH

022051Orig1s017

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**CENTER FOR DRUG EVALUATION AND
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APPLICATION NUMBER:

022051Orig1s017

APPROVAL LETTER



NDA 022051/S-017

SUPPLEMENT APPROVAL

GlaxoSmithKline Consumer Healthcare
Attention: Michael Cammarata
Manager, US Regulatory Affairs
184 Liberty Corner Road, Suite 200
Warren, NJ 07059

Dear Mr. Cammarata:

Please refer to your Supplemental New Drug Application (sNDA) dated and received February 23, 2017, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Flonase Sensimist Allergy Relief (fluticasone furoate) nasal spray, 27.5 mcg per spray.

This “Changes Being Effected” supplemental new drug application provides for correction of an error in the labeling regarding the fill volume statement.

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.

Remove the “NEW” flag on the upper left side of the front blister cards and front panel as this product line has been marketed for over 6 months.

LABELING

Submit final printed labeling, with the revisions listed above, as soon as they are available, but no more than 30 days after they are printed. The final printed labeling must be identical to submitted labeling described in the table below, with the removal of the “NEW” flag referenced above, and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

Submitted Labeling	Date Submitted
30-spray count carton (professional sample)	February 23, 2017
30-spray count bottle front	February 23, 2017
60-spray count blister card	February 23, 2017
60-spray count bottle front	February 23, 2017

120-spray count blister card	February 23, 2017
120-spray count bottle front	February 23, 2017
2 x 120-spray count blister card	February 23, 2017
3 x 120-spray count blister card front	February 23, 2017
60-spray count (Children's) blister card	February 23, 2017
60-spray count (Children's) bottle front	February 23, 2017

The final printed labeling should be submitted electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3)*. For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 022051/S-017.**” 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.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, 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(s) 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).

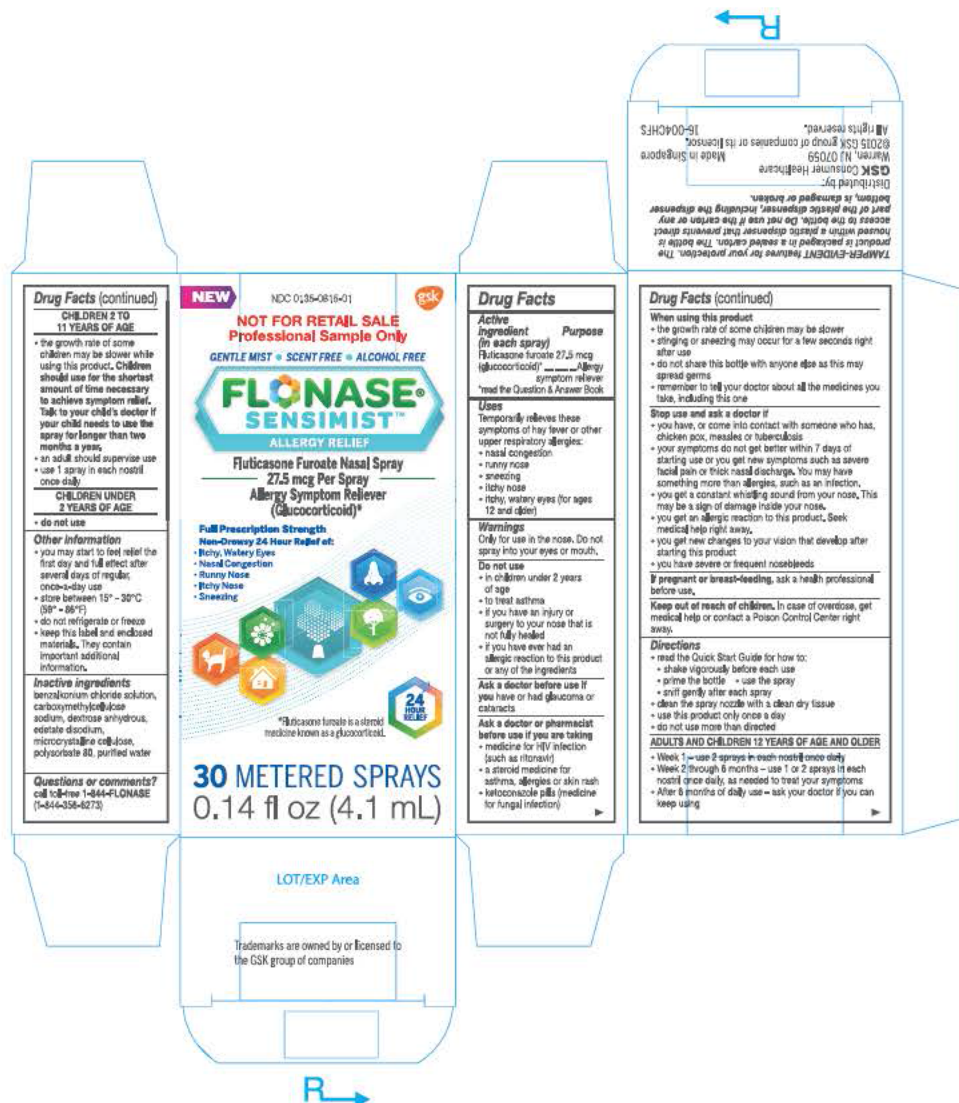
If you have any questions, call Sherry Stewart, Regulatory Project Manager, at (301) 796-9618.

Sincerely,

{See appended electronic signature page}

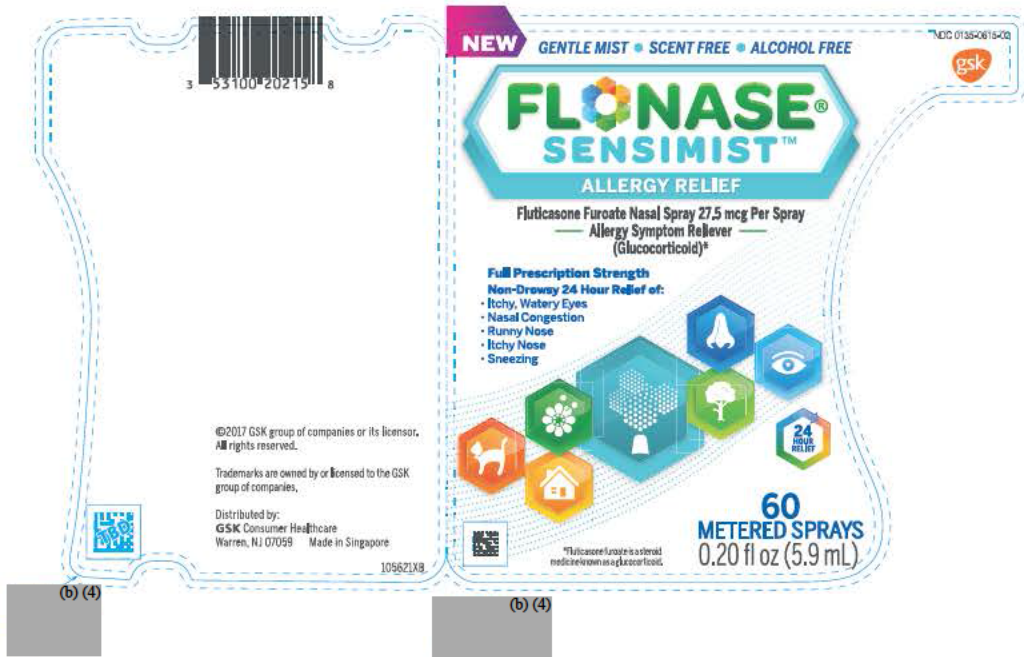
Theresa Michele, MD
Director
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

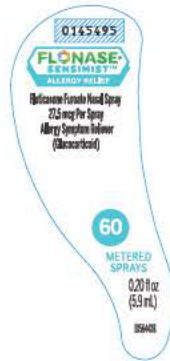
ENCLOSURES:
Carton and Container Labeling





(b) (4)





Page 1 of 2

(b) (4)

(b) (4)

(b) (4)



NEW

GENTLE MIST • SCENT FREE • ALCOHOL FREE

NDC 0135-0615-031



FLONASE[®]
SENSIMIST[™]

ALLERGY RELIEF

Fluticasone Furoate Nasal Spray 27.5 mcg Per Spray
— Allergy Symptom Reliever —
(Glucocorticoid)*

Full Prescription Strength
Non-Drowsy 24 Hour Relief of:

- Itchy, Watery Eyes
- Nasal Congestion
- Runny Nose
- Itchy Nose
- Sneezing



120
METERED SPRAYS
0.31 fl oz (9.1 mL)

*Fluticasone furoate is a steroid medicine known as a glucocorticoid.

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105623XB



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Page 1 of 2

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105666XA

TWIN PACK

NDC 0135-0615-05



GENTLE MIST • SCENT FREE • ALCOHOL FREE

FLONASE[®]
SENSIMIST[™]

ALLERGY RELIEF

Fluticasone Furoate Nasal Spray 27.5 mcg Per Spray
— Allergy Symptom Reliever —
(Glucocorticoid)*

**Full Prescription Strength
Non-Drowsy 24 Hour Relief of:**

- Itchy, Watery Eyes
- Nasal Congestion
- Runny Nose
- Itchy Nose
- Sneezing



*Fluticasone furoate is a steroid
medicine known as a glucocorticoid.



Two bottles
120 sprays per bottle

0.62 fl oz (18.2 mL) total
0.31 fl oz (9.1 mL) each

(b) (4)

(b) (4)

(b) (4)

NEW GENTLE MIST • SCENT FREE • ALCOHOL FREE

NDC 0115-0815-04



FLONASE[®] SENSIMIST[™]

ALLERGY RELIEF

Fluticasone Furoate Nasal Spray 27.5 mcg Per Spray
— Allergy Symptom Reliever —
(Glucocorticoid)*

Full Prescription Strength Non-Drowsy 24 Hour Relief of:

- Itchy, Watery Eyes
- Nasal Congestion
- Runny Nose
- Itchy Nose
- Sneezing



*Fluticasone furoate is a steroid medicine known as a glucocorticoid.

106552XB

(b) (4)



3 Bottles / 0.31 fl oz (9.1 mL) each
0.93 fl oz (27.3 mL) total

NO COPY
Cutout
Area

Three bottles
120 sprays per bottle

(b) (4)



NEW

GENTLE MIST • SCENT FREE • ALCOHOL FREE

AGES
2
YEARS
& OLDER

NDC 0135-0816-011



CHILDREN'S

FLONASE[®]
SENSIMIST[™]

ALLERGY RELIEF

Fluticasone Furoate Nasal Spray 27.5 mcg Per Spray
— Allergy Symptom Reliever —
(Glucocorticoid)*

**Full Prescription Strength
Non-Drowsy 24 Hour Relief of:**

- Nasal Congestion
- Runny Nose
- Itchy Nose
- Sneezing



24
HOUR
RELIEF

60
METERED SPRAYS
0.20 fl oz (5.9 mL)

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105625XA



*Fluticasone furoate is a steroid
medicine known as a glucocorticoid.

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/s/

THERESA M MICHELE
08/23/2017

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

022051Orig1s017

OTHER REVIEW(S)

Labeling Review for Flonase SensimistTM Allergy Relief

SUBMISSION DATES:	February 23, 2017
NDA/SUBMISSION TYPE:	22051/ CBE-0/S-017
ACTIVE INGREDIENTS:	Fluticasone furoate 27.5 mcg/spray
DOSAGE FORM:	Nasal spray, metered
SPONSOR:	GlaxoSmithKline Consumer Healthcare 184 Liberty Corner Rd. Suite 200 Warren, NJ 07059 Michael Cammarata Manager, U.S. Regulatory Affairs (201) 602-8156
REVIEWER:	Michelle D. Walker, PhD IDS Pharmacologist, DNDP
TEAM LEADER:	Steven Adah, PhD Lead Chemist, DNDP
PROJECT MANAGER:	Sherry Stewart, PharmD Regulatory Project Manager, DNDP

I. BACKGROUND

On February 23, 2017, the sponsor submitted a CBE-0 supplement for NDA 22051. The CBE-0 is for revision of the fill volume label statements for Flonase Sensimist Allergy Relief products. The sponsor referenced NDA 22051 S-013 submitted on October 2, 2015 for the Rx-to-OTC switch of Veramyst (fluticasone Furoate) nasal spray. According to CMC's review (S-17, uploaded to Panorama 7/19/17) OGD determined that an ANDA of the same drug product had a fill volume discrepancy between the bottle specification and the fill volume stated on the label in S-013. The sponsor was contacted by DNDP via email (12/22/2016) and was instructed to submit a new supplement to correct the calculation error on the labeling.

The fill volume was corrected for certain SKUs under this NDA in supplement 14. This supplement corrects the remaining SKU labels. The sponsor submitted labeling listed in the table below:

Submitted Labeling	Date of Submissions
30-spray count carton (professional sample)	2/23/2017
30-spray count bottle front	2/23/2017
60-spray count blister card	2/23/2017
60-spray count bottle front	2/23/2017
120-spray count blister card	2/23/2017
120-spray count bottle front	2/23/2017
2 x 120-spray count blister card	2/23/2017
3 x 120-spray count blister card front	2/23/2017
60-spray count (Children's) blister card	2/23/2017
60-spray count (Children's) bottle front	2/23/2017

*No representative SKUs were submitted

II. REVIEWER'S COMMENTS

The labeling that the sponsor submitted is reviewed below. The submitted proposed Flonase Sensimist labeling was compared to the currently approved labeling (dated August 2, 2016) that was approved under NDA 22051/S-013.

A. Principal Display Panel (PDP)

1. General appearance

The general information on the PDP is identical to the last approved labeling for the labeling listed below:

30-spray count carton (professional sample)
60-spray count blister card
60-spray count bottle front
120-spray count blister card
2 x 120-spray count blister card
3 x 120-spray count blister card front

60-spray count (Children's) blister card
--

The font on the lower right indicating total number of sprays on the 60-spray blister card, 120-spray front blister card, and Children's 60-spray blister card is changed to blue from green.

Reviewer's comment: *This is acceptable*

2. Change to the net quantity of contents

On February 23, 2017, we received a submission from the sponsor with updated labeling that provided a revised fill volume for the bottles. The sponsor provided the following table listing the original fill volumes and the revised fill volume for each spray count container:

Spray count	Original fill volume statement (fl oz)	Original fill volume statement (mL)	Revised fill volume statement (fl oz)	Revised fill volume statement (mL)
30-count	0.24	6.9	0.14	4.1
60-count	0.34	9.9	0.20	5.9
120-count	0.54	15.8	0.31	9.1
2 x 120-count	1.08	31.6	0.62	18.2
3 x 120-count	1.62	47.4	0.93	27.3

Reviewer's comment: *From a labeling review perspective, is the revised labels are acceptable. CMC has determined that this revised fill volume is correct in its review (submitted to Panorama: 07/19/2017).*

3. "NEW" flag

There is a "NEW" flag on the upper left side of the front blister cards and front panel (30-spray count carton) of the products listed below:

30-spray count carton (professional sample)
60-spray count blister card
120-spray count blister card
3 x 120-spray count blister card front
60-spray count (Children's) blister card

Reviewer's comment: *This is unacceptable. The "NEW" flag must be removed from the PDP since it has been more than six months since this product was marketed.*

B. Drug Facts Label (DFL)

1. Drug Facts label (DFL)

The DFL on the 30-spray count carton (professional sample) is identical to the last approved labeling. The sponsor did not submit DFL for the other spray count containers since the fill volume label statements are only on the front labels and blister cards. The cards and panels containing the DFL do not display the fill volume label statements.

Reviewer's comment: *This is acceptable. The sponsor stated that the only labeling that is being revised is the submitted labeling for the current supplement for NDA 22051, which displays the fill volumes. The other labeling is the same as the last approved labeling (Email: 5/10/2017).*

II. RECOMMENDATIONS

The submitted labeling is acceptable from a labeling perspective. CMC has confirmed that the revised fill volume is acceptable. The sponsor should be instructed to remove the "NEW" flag from the PDP in the final labeling, since it has been more than six months since this product was marketed. This change should be submitted as part of the sponsor's final labeling.

Issue an APPROVAL letter to the sponsor and request that the sponsor submit final printed labeling for the Flonase Sensimist labels listed in the table below:

Submitted Labeling	Date Submitted
30-spray count carton (professional sample)	February 23, 2017
30-spray count bottle front	February 23, 2017
60-spray count blister card	February 23, 2017
60-spray count bottle front	February 23, 2017
120-spray count blister card	February 23, 2017
120-spray count bottle front	February 23, 2017
2 x 120-spray count blister card	February 23, 2017
3 x 120-spray count blister card front	February 23, 2017
60-spray count (Children's) blister card	February 23, 2017
60-spray count (Children's) bottle front	February 23, 2017

The labeling must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

The Sponsor should be reminded that the “NEW” flag on the upper left side of the front blister cards and front panel must be removed as this product line has been marketed for over 6 months. Those labels that still have the “New” flag should be revised and submitted in the FPL.

III. SUBMITTED LABELING

17 Page(s) of Draft Labeling has been Withheld in Full as b4 (CCI/TS) immediately following this page

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/s/

MICHELLE D WALKER
08/16/2017

STEVEN A ADAH
08/16/2017

Filing Review for Flonase[®] Sensimist

SUBMISSION DATES:	February 23, 2017
NDA/SUBMISSION TYPE:	22051/ CBE-0/S-017
ACTIVE INGREDIENTS:	Fluticasone furonate 27.5 mcg/spray
DOSAGE FORM:	Nasal spray, metered
SPONSOR:	GlaxoSmithKline Consumer Healthcare 184 Liberty Corner Rd. Suite 200 Warren, NJ 07059 Michael Cammarata Manager, US Regulatory Affairs (201) 602-8156
REVIEWER:	Michelle D. Walker, PhD IDS Pharmacologist, DNDP
TEAM LEADER:	Steven Adah PhD Lead Chemist, DNDP
PROJECT MANAGER:	Sherry Stewart, PharmD Regulatory Project Manager, DNDP

The sponsor submitted a CBE-0 supplement to NDA 22051, to provide revised labeling with corrected fill volume statements for all affected label components of Flonase Sensimist Allergy Relief and Children's Flonase Sensimist Allergy Relief nasal spray. The fill volume statements for the Flonase Sensimist products were incorrect in the NDA 22051 S-013 supplement submitted on October 2, 2016 for the Rx-to-OTC switch of Veramyst (fluticasone furoate) Nasal Spray.

Submitted Labeling	Representative of Following SKUs
30-spray count carton (professional sample)	NA
30-spray count bottle front	NA

60-spray count blister card	NA
60-spray count bottle front	NA
120-spray count blister card	NA
120-spray count bottle front	NA
2 x 120-spray count blister card	NA
3 x 120-spray count blister card front	NA
60-spray count (Children's) blister card	NA
60-spray count (Children's) bottle front	NA

Issues	Yes/No	Comments
Is the supplement correctly assigned as a PA, CBE0, CBE30?	Yes	This is a CBE-0 supplement
Are the outer container and immediate container labels, and consumer information leaflet and other labeling included for all submitted SKUs?	No	Only the affected labeling that lists the fill volume statements was submitted.
If representative labeling is submitted, does the submitted labeling represent only SKUs of different count sizes (same flavor and dosage form)?	NA ¹	No representative labeling.
Is distributor labeling included?	No	
Does the submission include the annotated specifications for the Drug Facts label?	NA	No DFL submitted
Is Drug Facts title and Active ingredient/Purpose section of Drug Facts label visible at time of purchase?	NA	No DFL submitted
Do any of the labels include "prescription strength" or similar statements?	Yes	There is a "full prescription strength" statement on the PDP
Do any of the labels include "#1 doctor recommended" or similar endorsement statements?	No	
Do any labels include text in a language other than English?	No	
Is a new trade name being proposed? If multiple trade names, is the primary or preferred trade name identified?	No	
Does a medical officer need to review any clinical issues?	No	
If SLR, should ONDQA also review?	NA	CMC should confirm that the revised fill volumes are correct before DNDP can approve the labeling.

Not Applicable

Reviewer's Comment:

No additional information needs to be submitted for this review. All of the affected labeling was submitted for review.

Information Request:

NA

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/s/

MICHELLE D WALKER
04/12/2017

STEVEN A ADAH
04/12/2017

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

022051Orig1s017

ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS

Stewart, Sherry

From: Stewart, Sherry
Sent: Friday, May 05, 2017 11:14 AM
To: Michael Cammarata (michael.x.cammarata@gsk.com)
Subject: NDA 22051 S-17, Flonase Sensimist -Request for Information - Response Required

Hi Michael,
Please reply to this email to confirm receipt.

We have the following request for information with regard to the above referenced CBE-0 supplement currently under review:

1. We note that you did not submit complete labeling, including the Drug Facts Label (DFL) for the above referenced sNDA. For example the following pieces of labeling were not included (note this is a partial list): 30-, 60-, 60-(Children's) and 120 spray count immediate container back label, Question Answer Booklet, Quick Start Guide, and the Question and Answer Leaflet.

Confirm that all pieces of labeling, other than those included with this supplement, will not change from the last approval.

If there are any changes to any of the other pieces of labeling, that have not been submitted with this supplement, please submit such labeling via email to me and follow up with an official amendment to the supplement by close of business May 12, 2017.

If you have any questions, please let me know.

Thank you and best regards,

Sherry Stewart, PharmD

Regulatory Project Manager

Division of Nonprescription Drug Products

Office of Drug Evaluation IV

Center for Drug Evaluation and Research

301-796-9618

Sherry.Stewart@fda.hhs.gov

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/s/

SHERRY A STEWART
05/05/2017



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022051/S-017

**CBE SUPPLEMENT –
ACKNOWLEDGEMENT**

GlaxoSmithKline Consumer Healthcare
Attention: Michael Cammarata
Manager, US Regulatory Affairs
184 Liberty Corner Road, Suite 200
Warren, NJ 07059

Dear Mr. Cammarata

We have received your Supplemental New Drug Application (sNDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA or the Act) for the following:

NDA NUMBER:	022051
SUPPLEMENT NUMBER:	017
PRODUCT NAME:	FLONASE SENSIMIST ALLERGY RELIEF (fluticasone furoate) nasal spray, 27.5 mcg per spray
DATE OF SUBMISSION:	FEBRUARY 23, 2017
DATE OF RECEIPT:	FEBRUARY 23, 2017

This supplemental application, submitted as a “Changes Being Effected” supplement, proposes the following change: correction of an error in the labeling regarding the fill volume statement.

We have not received the following information: the data (calculations) on which the change is based.

We identified this deficiency during our initial administrative review. We suggest that you submit this information to us as soon as possible but no later than 10 days after the date of receipt of this letter.

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, we will file the application on April 24, 2017 in accordance with 21 CFR 314.101(a).

If the application is filed, the user fee goal date will be August 23, 2017.

Cite the application number listed above at the top of the first page of all submissions to this application. Send all submissions, electronic or paper, including those sent by overnight mail or courier, to the following address:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Nonprescription Drug Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

All regulatory documents submitted in paper should be three-hole punched on the left side of the page and bound. The left margin should be at least three-fourths of an inch to assure text is not obscured in the fastened area. Standard paper size (8-1/2 by 11 inches) should be used; however, it may occasionally be necessary to use individual pages larger than standard paper size.

Non-standard, large pages should be folded and mounted to allow the page to be opened for review without disassembling the jacket and refolded without damage when the volume is shelved. Shipping unbound documents may result in the loss of portions of the submission or an unnecessary delay in processing which could have an adverse impact on the review of the submission. For additional information, see

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/DrugMasterFilesDMFs/ucm073080.htm>.

If you have questions, call me at (301) 796-9618.

Sincerely,

{See appended electronic signature page}

Sherry A. Stewart, PharmD
Senior Regulatory Project Manager
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

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/s/

SHERRY A STEWART
04/10/2017

Stewart, Sherry

From: Jiang-Baucom, Ping
Sent: Tuesday, April 04, 2017 11:48 AM
To: Stewart, Sherry; Okubadejo, Olugbenga (Gbenga); Raghavachari, Ramesh
Cc: Adah, Steven; Walker, Michelle
Subject: RE: NDA022051/S-017

Hi Sherry,

Here is what proposed in S017:

Table 1. Original and Revised Labeled Fill Volume Statements

Spray Count	Original Fill Volume Statement (fl oz)	Original Fill Volume Statement (mL)	Revised Fill Volume Statement (fl oz)	Revised Fill Volume Statement (mL)
30-count	0.24	6.9	0.14	4.1
60-count	0.34	9.9	0.20	5.9
120-count	0.54	15.8	0.31	9.1
2 x 120-count	1.08	31.6	0.62	18.2
3 x 120-count	1.62	47.4	0.93	27.3

There is no calculation provided in the supplement. For me to verify the calculation, we need to request the applicant to provide the information.

Here is the bottle specification used in the spray pump:

Note all the spray configurations use same type of bottles. Proposed fill volumes for all configurations are within the fill capacity of the bottles.

From CMC, there is no issue.

Provided in this email is a quick look of supplement to address your urgent questions. I will need more time to do a full review for this supplement and get concurrence from my branch chief.

Please do not hesitate to call me should you have any questions.

Thanks,
Ping

From: Stewart, Sherry
Sent: Tuesday, April 04, 2017 11:00 AM
To: Jiang-Baucom, Ping; Okubadejo, Olugbenga (Gbenga); Raghavachari, Ramesh
Cc: Adah, Steven; Walker, Michelle
Subject: RE: NDA022051/S-017

Hi Ping, please let me know as soon as you have had a look. This is due tomorrow, and we have to get the labeling review finalized and final clearance on the letter.

Thanks so much!

Sherry

From: Jiang-Baucom, Ping
Sent: Monday, April 03, 2017 3:09 PM
To: Stewart, Sherry; Okubadejo, Olugbenga (Gbenga); Raghavachari, Ramesh
Cc: Adah, Steven; Walker, Michelle
Subject: RE: NDA022051/S-017

Hi Sherry,

Called You but got no answer.

I will look at this supplement tomorrow and get back to you.

Thanks,
Ping

From: Stewart, Sherry
Sent: Monday, April 03, 2017 12:50 PM
To: Okubadejo, Olugbenga (Gbenga); Jiang-Baucom, Ping; Raghavachari, Ramesh
Cc: Adah, Steven; Walker, Michelle
Subject: RE: NDA022051/S-017
Importance: High

Hi Ping,

Could you call me when you get a chance?

Briefly though,

We need to have an email from you stating whether or not the calculations for the fill volume are acceptable for this supplement. The labeling for supplement 14 depends on it, and our action date for that is 4/5. Sorry for the rush, it is a situation we just came to fully realize.

Thanks,

Sherry

From: Okubadejo, Olugbenga (Gbenga)
Sent: Monday, April 03, 2017 11:26 AM
To: Stewart, Sherry; Jiang-Baucom, Ping; Raghavachari, Ramesh
Subject: NDA022051/S-017

Hi Sherry,

Please see below.

Ping and Ramesh - Please confirm CBE-30 is correct filing category per Don's message below



Donald Klein marked this as Done and set the status to **Complete**.

N22-051, S-017; DUE 8/23/17
DNDP is managing this supplement
CBE-0 is the wrong Reporting Category for CMC
Please change this to a CBE-30

The CMC Reviewer should check the NDA and the proposed change prior to March 23.
In the event there is a major CMC issue then this should be changed to a PAS.

No sites need to be submitted

No consults are needed

Proposed Change: Labeling revised to correct the fill volume.

Assigned to Ping since she is the DNDP CMC Expert.

 5 · Mar 10 at 12:40 pm · [Like](#)

Thanks,
Gbenga

-----Original Message-----

From: Stewart, Sherry
Sent: Monday, April 03, 2017 11:11 AM
To: Okubadejo, Olugbenga (Gbenga)
Subject: RE: Successfully Processed ECTD: NDA022051 in DARRTS.
Importance: High

Hi Gbenga,

I sent this to Ryan a week or so ago, but now I think you're the one who should get it. Is that correct?

Can you provide me with an assignment, our division has a somewhat urgent question about this, and needs to take action by 4/5/17.

Thanks,

Sherry

-----Original Message-----

From: Stewart, Sherry

Sent: Thursday, March 23, 2017 2:20 PM

To: Zettle, Ryan

Subject: FW: Successfully Processed ECTD: NDA022051 in DARRTS.

Hi Ryan,

Please see this CBE-o supplement, I've also attached an email with background. They are a little delayed in submitting the CBE-o, it was supposed to come in by 2/24 but I don't think we're going to quibble over that.

Since there is a labeling included in this one, so DNDP will manage it.

Could you provide me with a reviewer assignment for it?

Thanks,

Sherry

-----Original Message-----

From: Brum, Dan

Sent: Thursday, March 23, 2017 9:47 AM

To: Stewart, Sherry

Subject: FW: Successfully Processed ECTD: NDA022051 in DARRTS.

Sherry,

Probably let generics (and CMC) know that this arrived so the mistake can be addressed.

Thanks,

--Dan

-----Original Message-----

From: asr-dontreply@fda.hhs.gov [mailto:asr-dontreply@fda.hhs.gov]

Sent: Wednesday, March 22, 2017 4:35 PM

To: IntegrityServices; CDER-EDROIM; CDER-EDR_ASR_Document_Coordinators; CDER-EDRSTAFF; CDER-EDRADMIN; CDER ESUB; CDER-EDROIM; CDER-OND-DNDP-EDRNOTIFY; Stewart, Sherry

Subject: Successfully Processed ECTD: NDA022051 in DARRTS.

Successfully Processed ECTD: NDA022051 in DARRTS. Details below:

Transmittal Form: <http://darrrts.fda.gov/darrrts/indTransForm.do?suppDocumentId=10305659>

EDR Location: \\CDSESUB1\evsprod\NDA022051\022051.enx

For Document Room Staff Use:

DTD Version: 2.01

Application Type/Number: NDA022051

Incoming Document Category/Sub Category: Electronic_Gateway

Supporting Document Number: 515

eCTD Sequence Number: 0092

Letter Date: 3/22/2017

Stamp Date: 3/22/2017

Receipt Date/Time from Notification: 3/22/2017 2:50:49 PM

Origination Date/Time from Notification: 3/22/2017 2:49:51 PM

DOCUMENT ID: 6288017

Cover Letter: \\CDSESUB1\evsprod\NDA022051\0092\m1\us\cover-letter.pdf

356H Form: \\CDSESUB1\evsprod\NDA022051\0092\m1\us\356h.pdf

2252 Form: NOT FOUND

2253 Form: NOT FOUND

3397 Form: NOT FOUND

3674 Form: NOT FOUND

For EDR Staff Use:

The submission has already been processed. The following information is provided if verification is required. No additional action is required on your part

EDR Location: \\CDSESUB1\evsprod\NDA022051\0092

Submission Size: 12655103

Gateway Location: \\FDSWV19612-prd\CDER\inbound\ECTD\ci1490208582099.16091108@fduv08640_te2

CoreID: ci1490208582099.16091108@fduv08640_te2

Copy to EDR Status: Good-1. Files were copied successfully.

For CDER Project Manager Use:

The following submission received through the Electronic Submission Gateway has been processed using the following information. This information will be updated once Document Room personnel have been able to verify the content of the submission.

Application Type/Number: NDA022051

Incoming Document Category/Sub Category: Electronic_Gateway

Supporting Document Number: 515

eCTD Sequence Number: 0092

Letter Date: 3/22/2017

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

/s/

SHERRY A STEWART
04/05/2017