	RECORD	
dbv technologies	**SAE FORM**	
Reference: F-MED-008-E	**Version:** 1.0	**Application date:** *24 Nov 2017*

Study name	VIASKIN PEANUT EXPANDED ACCESS PROGRAM		
Country	USA	**PRODUCT**	Viaskin Peanut 250 mcg
Principal Investigator's name			
Address			
Telephone		**E-mail**	

SUBJECT'S ID (RID NUMBER):

Gender	**Date of birth**	**Weight**	**Height**
☐ male ☐ female	⌊_⌊_⌋ / ⌊_⌊_⌊_⌋ / ⌊_⌊_⌊_⌊_⌋	⌊_⌊_⌊_⌋ . ⌊_⌋ kg	⌊_⌊_⌊_⌋ cm

SAE: ***Report should be sent to DBV within 24 hours:*** pharmacovigilance@dbv-technologies.com

Report type	☐ Initial	☐ Follow-Up	Follow-Up number ⌊_⌋
Corresponding Adverse event record number (as in CRF)	⌊_⌋		

Adverse event
(diagnosis, if possible)

Onset	**Resolution**
Date ⌊_⌊_⌋ / ⌊_⌊_⌊_⌋ / 2 0 ⌊_⌊_⌋ (DD / MMM / YYYY)	**Date** ⌊_⌊_⌋ / ⌊_⌊_⌊_⌋ / 2 0 ⌊_⌊_⌋ (DD / MMM / YYYY)
Time ⌊_⌊_⌋ / ⌊_⌊_⌋ (HH / mn)	**Time** ⌊_⌊_⌋ / ⌊_⌊_⌋ (HH / mn) or ☐ ongoing

Seriousness criteria (mark (**X**) all that apply)

☐ Death Date of death: ⌊_⌊_⌋ / ⌊_⌊_⌊_⌋ / 2 0 ⌊_⌊_⌋ (DD / MMM / YYYY)

Autopsy done? ☐ Yes *(attach report)* ☐ No ☐ unknown

☐ Life threatening

☐ Requires subject hospitalization or prolongs existing hospitalization

Date of admission: ⌊_⌊_⌋ / ⌊_⌊_⌊_⌋ / 2 0 ⌊_⌊_⌋ (DD / MMM / YYYY) Date of discharge: ⌊_⌊_⌋ / ⌊_⌊_⌊_⌋ / 2 0 ⌊_⌊_⌋ (DD / MMM / YYYY)

☐ Persistent or significant disability/incapacity

☐ Congenital anomaly/birth defect

☐ Medically significant (may jeopardize the patient or require intervention to prevent one of the outcomes listed above). EXPLAIN IN NARRATIVE.

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Intensity/Severity: ☐ mild ☐ moderate ☐ severe

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SUBJECT'S ID (RID NUMBER):

Report type	☐ Initial ☐ Follow-Up Follow-Up number ⌊_⌋

Outcome of the event *(at the time of last observation)*

☐ resolved (recovered/stabilized) ☐ not resolved (recovering or not yet recovered)

☐ resolved with sequelae ☐ fatal ☐ unknown

Specify sequelae:

Investigational product:

Start date

⌊_⌋⌊_⌋/⌊_⌋⌊_⌋⌊_⌋/⌊_⌋⌊_⌋⌊_⌋⌊_⌋
DD MMM YYYY

Date of last application prior to event:

⌊_⌋⌊_⌋/⌊_⌋⌊_⌋⌊_⌋/⌊_⌋⌊_⌋⌊_⌋⌊_⌋
DD MMM YYYY

Blind broken ☐ No ☐ Yes

Date: ⌊_⌋⌊_⌋/⌊_⌋⌊_⌋⌊_⌋/2 0⌊_⌋⌊_⌋
DD MMM YYYY

☐ Open label; if yes precise start date in open label

⌊_⌋⌊_⌋/⌊_⌋⌊_⌋⌊_⌋/2 0⌊_⌋⌊_⌋
DD MMM YYYY

Daily dose and route of administration	

Action taken with investigational product

☐ Not applicable ☐ Application duration not changed ☐ Application duration changed – specify:

.....

☐ Drug interrupted Stop date ⌊_⌋⌊_⌋/⌊_⌋⌊_⌋⌊_⌋/2 0⌊_⌋⌊_⌋
DD MMM YYYY

Restart date ⌊_⌋⌊_⌋/⌊_⌋⌊_⌋⌊_⌋/2 0⌊_⌋⌊_⌋
DD MMM YYYY

☐ Drug withdrawn (permanently discontinued) Stop date ⌊_⌋⌊_⌋/⌊_⌋⌊_⌋⌊_⌋/2 0⌊_⌋⌊_⌋
DD MMM YYYY

☐ Other, describe: _____

If investigational product interrupted, did the AE stop? ☐ Yes ☐ No ☐ NA	If reintroduced, did the AE recur? ☐ Yes ☐ No ☐ NA

Other actions taken

☐ None

☐ Therapeutic or diagnostic procedure

☐ Emergency visit If yes state the duration:

☐ Corrective medication (medication taken specifically for this AE, please specify below)

☐ Other: specify in narrative

Study name	VIASIN PEANUT EXPANDED ACCESS PROGRAM

SUBJECT'S ID (RID NUMBER):

Report type	☐ Initial ☐ Follow-Up Follow-Up number ⌴⌴

Concomitant medications / Corrective medications

Medication (Generic/Brand)	**Total daily dose**	**Unit**	**Route**	**Freq.**	**Indication**	**corrective treatment?** (Y/N)	**Start date** (dd-mmm-yyyy)	**Ongoing**	**Stop date** (dd-mmm-yyyy)
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	RECORD	
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Study name	VIASKIN PEANUT EXPANDED ACCESS PROGRAM
SUBJECT'S ID (RID NUMBER)	
Report type	☐ Initial ☐ Follow-Up Follow-Up number ⌊_⌋

Summary of SAE

Description of symptoms and course of events in chronological order

Relationship with investigational product (tick one)

☐ No relationship ☐ unlikely ☐ Possibly ☐ Probably ☐ Related

☐ Related to study procedure.

comment on possible alternative reasons:

Number of pages enclosed for attached documents:	

To the best of my knowledge, all information recorded on this SAE form is correct

Investigator

Date ⌊_⌋⌊_⌋/⌊_⌋⌊_⌋⌊_⌋/⌊2⌋⌊0⌋⌊_⌋⌊_⌋
DD MMM YYYY

(Signature)

***Please send the* SAE to:** pharmacovigilance@dbv-technologies.com
within 24 hours of becoming aware of this SAE

Report received on:

Date ⌊_⌋⌊_⌋/⌊_⌋⌊_⌋⌊_⌋/⌊2⌋⌊0⌋⌊_⌋⌊_⌋
DD MMM YYYY