



DEPARTMENT OF HEALTH & HUMAN SERVICES
FDA/CBER/OVRR/DVRPA

Memorandum

Date: January 23, 2020

From: Daphne D. Stewart, CSO
Regulatory Management Support Branch,
HFM-475, DVRPA/OVRR

Through: Tim D. Nelle, Ph.D., CAPT U.S. Public Health Service,
Branch Chief, RMSB

To: **BLA STN** 125696/0 File

Subject Review of Aimmune Therapeutics, Inc. – BLA 125696/0
Peanut [*Arachis hypogaea*] Allergen Powder - dnfp – Palforzia®

Background

Peanut [*Arachis hypogaea*] Allergen Powder - dnfp – Palforzia® for treatment to reduce the risk of anaphylaxis after accidental exposure to peanut in patients aged 4 to 17 years with a confirmed diagnosis of peanut allergy. This submission contains the following labels that are the subject of this review:

- 1 Initial Dose Escalation Carton (IDE) Label
- 10 Individual Blister Carton Physician Sample Labels
 - 3 mg, 6 mg, 12 mg, 20 mg, 40 mg, 80 mg, 120 mg, 160 mg, 200 mg, 240 mg
- 10 Daily Dose Pack Carton Labels
 - 3 mg, 6 mg, 12 mg, 20 mg, 40 mg, 80 mg, 120 mg, 160 mg, 200 mg, 240 mg
- 5 Sachet and Carton Labels
 - Sachet (Physician Sample), Sachet (Up-Dosing and Maintenance), Sachet Carton-15 count (Up-Dosing), Sachet Carton-30 count (Maintenance)

These labels were reviewed for compliance with the regulations 21 CFR 201.25 & 21 CFR 207.35 (3)(i), 21 CFR 207.35, Subpart G – Labeling Standards 21 CFR 610.60 (a)(1) through (7) and 21 CFR 610.60 (7) (b) through (e), 21 CFR 610.62 (a) through (c), 21 CFR 610.63, 21 CFR 610.64, 21 CFR 610.67, the Drug Supply Chain Security Act (DSCSA) and CBER Job Aid 900.08: National Drug Code, Bar Code and Product Identifier. To ensure completeness, the CBER checklists were used during this review; however, only the checklists for the final draft labels are attached to this review (see Appendixes). In each checklist, an “x” next to each item denotes that the label was found to be compliant with the corresponding regulation. Portions of these labels that were found to not be in compliance with regulations are discussed below.

Review of carton and container labels submitted December 21, 2018 and April 29, 2019:

The primary differences between the carton and container labels submitted on December 21, 2018, and those submitted on April 29, 2019, are inclusion of the proposed brand name, “PALFORZIA”, and a minor correction to the proper name presentation. Given these minor differences, and the fact the review issues identified were the same for both versions, the review of both sets of labels are covered together in this section.

Initial Dose Escalation Carton Label

The following observations were noted for the Initial Day Escalation (IDE) Carton Label:

- The proper name should be above the tradename, per 21 CFR 610.62(a).
- The proper name should be at least as prominent as the tradename, per 21 CFR 610.62(b).

Individual Blister Carton Physician Sample Labels

The regulations under 21 CFR 200s do not provide an option for marking a label with the words “Physician Sample”. This issue was discussed in several internal meetings and it was decided that the closest similar was the term “Drug Sample”. Under 21 CFR 203.3(i), “Drug sample means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.” After it was confirmed that the product to include with this label would be administered in the physician office and would be an integral part of the dosing regimen, it was determined these labels do not meet this requirement. See sections below for further discussion and resolution of this issue.

Daily Dose Pack Carton Labels

The following observations were noted for the Daily Dose Pack Package Labels:

- The proper name should be above the trade name, per 21 CFR 610.62(a).
- The proper name should be as prominent as the trade name, per 21 CFR 610.62(b).

Sachet and Carton Labels

The following observations were noted for the Sachet Container and Carton Labels:

- The 300 mg Sachet (Physician Sample) Container Label (appendix 4) (National Drug Code 71881-111-09) and the 300 mg Sachet – 15 count (Physician Sample) Carton Label (appendix 5) (National Drug Code 71881-111-99) do not meet the requirements for ‘samples labels’ under 21 CFR 203.3(i) because these products are administered in the physician office and are an integral part of the dosing

regimen (as discussed above). The text “Physician Sample” should be removed.

- For the 300 mg Sachet (Up-Dosing and Maintenance) Container Label (appendix 6)
(National Drug Code 71881-111-01):
 - a. The DataMatrix is missing from the label. The DataMatrix contains the Global Trade Item Number, Lot Number, Expiration Date, Serialization Number per online tradename is more prominent than the proper name per Product Identifier Requirements Under the Drug Supply Chain Security Act (DSCSA) (9)(B)(4).
 - b. The proper name should be above the trade name per 21 CFR 610.62(a).
 - c. The proper name should be at least as prominent as the trade name per (21 CFR 610.62(b)).
 - d. This cartons also contains artwork which appears more prominent than both the proper name and trade name. This issue will be addressed by Advertising and Promotional Labeling Branch (APLB).
- For the 300 mg the 15 count Sachet Carton (appendix 7)
(National Drug Code 71881-111-15) and the 30-count Sachet Carton (Maintenance) (National Drug Code 71881-111-30)):
 - a. The proper name should be above the trade name per (21 CFR 610.62(a))
 - b. The proper name should be at least as prominent as the trade name per (21 CFR 610.62(b)).
 - c. The cartons also contain artwork which appears more prominent than both the proper name and trade name. This issue should be addressed by Advertising and Promotional Labeling Branch (APLB).

The following information request (IR) concerning labeling was communicated to the sponsor on March 28, 2019:

In module 1.12.4 you have submitted draft carton and container labels for Physician samples. Please submit draft container and carton labels for commercial lots for CBER’s review and comment.

The sponsor responded on April 29, 2019, by submitting draft carton and container labels for all physician samples (individual blisters in 12 or 18 count cartons and sachets in 15 count cartons) and commercial product presentations (Initial Dose Escalation card, Daily Dose Packs, sachets in 15-count sachet cartons for up-dosing, and sachets in 30-count cartons for maintenance dosing). These labels were updated with proposed brand name, PALFORZIA, and include a correction to the proper name presentation. See section above for review comments for these labels.

On October 11, 2019, an advice and information request were sent to the sponsor. The sponsor responded in their November 8, 2019, submission. Below is a summary of each item requested, the sponsor's response, and our evaluation of their response:

1. *Please ensure the proper name listed on the draft carton and container.*

Sponsor response: Revised carton and container labels were proper name with the proper name "Peanut (Arachis hypogaea) Allergen Powder-dnfp".

Evaluation of sponsor's response: This is acceptable.

2. *Please capitalize the agreed upon trade name throughout the draft carton and container labels.*

Sponsor response: We are not in agreement with CBER's suggestion of capitalizing the tradename. We propose only capitalizing the first letter of the tradename like previous products such as Oralair, Enbrel and Herceptin.

Evaluation of sponsor's response: This is acceptable. The lettering for the container and carton labels need not adhere to all-cap recommendations.

3. *As per 21CFR 610.60 and 61, the US License number needs to be included on all the container and carton labels.*

Sponsor response: The "US License No.: xxxx as a placeholder was added to their labels since, the sponsor currently does not have a license number.

Evaluation of sponsor's response: This is acceptable.

4. *As per 21 CFR 610.62 (a) the proper name of the product should be placed above the trade name of the product in all the carton and container labels.*

Sponsor response: Prefers to keep the tradename above the proper name such as these products such as would like to Oralair, Enbrel and Herceptin.

Evaluation of sponsor's response: We did not agree with the sponsor's suggestion because it is not in compliance with 21 CFR 610.62(a). On January 6, 2020, CBER informed the sponsor this was not acceptable, and the sponsor should revise their labels. The sponsor did agree and

included this revision in their future draft labels. For additional information on the resolution of this issue, please see sections below.

5. *As per 21 CFR 610.62 (b) the point size for the proper name should be at least as prominent as the trade name of the product.*

Sponsor response: The labels submitted show that the tradename and proper name have been adjusted to be visual equal in prominence.

Evaluation of sponsor's response: This is acceptable.

6. *As per 21 CFR 203.3(i) the definition of drug sample is "a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug". Your up-dosing level cartons are labeled as "Physician sample - not for sale" The first dose of each up-dose level is administered in the physician office and is an integral part of the dosing regimen. These individual blister cartons and sachet cartons do not meet the definition of a drug sample under 21 CFR 203.3(i) and should not be labeled as a physician sample. Please acknowledge and comment.*

Resolution of this issue: After several rounds of discussions with the sponsor, it was decided that it was acceptable for sponsor to include the words "Physician sample – not for sale".

7. *Per Product Identifier Requirements Under the Drug Supply Chain Security Act (DSCSA) – Compliance Policy Guidance for Industry (IX)(4) the Human Readable Data encoded into the 2D barcode is not consistently included on all the draft carton and container labels. The full information is included only on 300 mg sachet carton-15 count (up-dosing) and 300 mg sachet carton- 30 count (maintenance). Please include this information on all the commercial cartons.*

Sponsor response: The submitted labels indicate that the physician samples are not considered commercial and will not contain the sterilization license plate black boxes.

Evaluation of sponsor's response: It is acceptable for the Label starter packs to be labeled as "Starter Pack," rather than as "Physician Sample – Not for Resale." Also note, Starter packs would be listed in the HOW SUPPLIED/STORAGE AND HANDLING section of the enclosed prescribing information.

8. *Please provide list of information that will be encoded within the 2D barcode on the carton labels.*

Sponsor response: The datamatrix code list will be submitted to include

on the carton labels such as S/N, GTIN, Lot & Exp. This information will be within a black box that will be located on all carton labels.

Evaluation of sponsor's response: This is acceptable.

On January 6, 2020, CBER sent additional IRs relating to the carton and container labeling (provided below in *italics*). The sponsor addressed each of them in their January 9, 2020, submission (also provided in *italics*). Our evaluation of each response is also provided.

1. *SPL style-sheets for the Prescribing Information (PI) will always convert the proprietary name lettering to all caps. Lettering for carton and container need not adhere to all-caps recommendation.*

Sponsor's response: They acknowledged the comment.

Evaluation of sponsor's response: This is acceptable

2. *As per 21 CFR §610.62(a), the proper name must be placed above the proprietary name in a symmetrical manner. Please revise the position of the proprietary name to be below the proper name to comply with the regulations.*

Sponsor's response: The sponsor submitted labels that were revised to have the proper name above the proprietary name.

Evaluation of sponsor's response: This is acceptable.

3. *The size of the barcode should not exceed that of, or be distracting to, the proper and proprietary names of the product.*

Sponsor response: The sponsor submitted labels that were revised with the removal of the barcodes from the blister and sachet labels due to size limitations.

Evaluation of sponsor's response: This is acceptable.

4. *The art work submitted to the BLA on November 12, 2019, includes art work for the 240 mg individual blister. The font size of "240 mg" is causing it to run into the GTIN under the barcode. Please adjust the size and the space.*

Sponsor response: This issue was also resolved by the removal of the barcodes from the blister and sachet labels.

Evaluation of sponsor's response: Initially upon reviewing this response, CBER did not agree, as per 21 CFR 201.25, *Bar code label requirements*, individual blisters and those sachets which will only be available as physician samples are exempt from including a machine readable, linear barcode. The individual sachets that will be commercially available for two weeks Up-dosing and daily maintenance dose must bear machine readable, linear barcode. This finding was communicated to the sponsor on January 16, 2020. Please see section below for additional information on this issue.

5. *According to 21 CFR §610, please include the name, address and license number of the product manufacturer on the container and carton in addition to 'manufactured for'.*

Sponsor response: The sponsor submitted labels that comply with 21 CFR 600.3(t) revised with the manufactured by: and their complete address for IDE kits, all the cartons and daily dose packs. For blisters and sachets per 21 CFR 610.60(c) size limited these labels will contain the name of the manufacture by: name only.

Evaluation of sponsor's response: This is acceptable.

6. *Your approach to assignment of NDC's is incorrect. You should assign a unique NDC product code to each dosage strength (0.5 mg, 1 mg, 10 mg, 20 mg, 100 mg and 300 mg) and then a separate unique NDC code for each co-packaged product (dose pack), as co-packaged products are considered "kits". For example, you currently have assigned a single NDC (71881-113-13) to the Initial Dose Escalation (IDE) card, but the IDE card contains both 0.5 mg and 1 mg dosage strength capsules. Instead, you should assign unique NDCs for the 0.5 mg capsule and the 1 mg capsule, then another NDC for the IDE card. Please revise your NDCs to include the assignment of unique NDCs for each dosage strength (0.5 mg, 1 mg, 10 mg, 20 mg, 100 mg, and 300 mg) and unique NDCs for each dose pack (carton).*

Sponsor response: The sponsor submitted a chart with their updated NDCs for the labels mentioned above.

Evaluation of sponsor's response: The information provided by the sponsor to address this issue is acceptable.

7. *Please add "For 4 through 17 years of age" on the front panel of the cartons.*

Sponsor response: The sponsor submitted labels that were revised to have the age range placed on the front panel of all the carton label.

Evaluation of sponsor's response: The proposed revisions are acceptable.

On January 16, 2020, FDA provided an email response to Aimmune's January 7, 2020 email query and to Aimmune's response to comments 3 and 5 for the carton and container labels in amendment 72 submitted to the BLA STN 125696 on January 10, 2020. Their responses are summarized below each IR item and is labeled as the "Sponsor Response". Evaluation of each response is also provided:

1. *CBERs IR : As per 21 CFR 201.25, Bar code label requirements, individual blisters and those sachets which will only be available as physician samples are exempt from including a machine readable, linear barcode. The individual sachets that will be commercially available for two weeks Up-dosing and daily maintenance dose must bear machine readable, linear barcode. Please submit both the sample and commercially available sachet container labels.*

Sponsor's response: The updated artwork for the sample and commercially available sachet container labels are provided, and they have re-instated the bar code on the individual sachets. This has been done for the physician samples as well as for the 2 weeks Up-dosing and daily maintenance sachets in order to maintain a consistent design for these items. Aimmune notes that the phrase 'For detailed information see medication guide' has been moved from the back panel of the sachet to the front panel to create room for the re-instated bar code. The bar code has been maintained at its current size to ensure readability when printed. In the case of the sachet, the bar code appears on the opposite side of the sachet from the proprietary name and brand name, so it will not be distracting to this label content.

Evaluation of Sponsor's response: This is acceptable.

2. *Sponsor's response to CBERs response: As per 21 CFR 600.3 (t) We have included the name, address, and license number of Aimmune as the product manufacturer on the IDE kit as well as all cartons and daily dose packs. This information will be presented as follows:*

*Manufactured by Aimmune Therapeutics
Brisbane, CA 94005
US License No.: XXXX
1-833-246-2566*

Evaluation of Sponsor's response: This is acceptable.

3. *CBERs has acknowledged that the manufacturer will be stated on the packaging for the IDE kit as well as all cartons and daily dose packs accordingly.*

Sponsor response: On January 7, 2020, in an email: Due to the lead time needed for printing the foil sachet, and as the updates requested in this request is relatively small, we would like to request authorization to use the version of the sachet text/graphics (Aimmune Design Draft REV 4) submitted as part of our response to IR #30 (SEQ 0050) for the initial launch stock and to change to the final text at the next print run.

It is anticipated that sachets with the previous text/graphics would be in use for approximately 3 months after which time we will transition to the final approved version. All final changes will be made for the sachet cartons for initial launch stock.

CBER response: Does not agree. Upon distribution, product carton and containers are required to have an approved label. A drug product may be misbranded under section 502(a) of the Federal Food, Drug, and Cosmetic Act if the labeling is false or misleading.

Sponsor response: CBERs response is acknowledged and Aimmune confirms that only the approved label will be used for commercialization.

Evaluation of Sponsor's response: This is acceptable.

Review of carton and container labels submitted January 18, 2020:

Initial Dose Escalation Carton Label

This revised carton label was reviewed and found to be satisfactory (see Appendix 1 for details).

Individual Blister Carton Physician Sample Labels

These revised labels were reviewed and found to be satisfactory (see Appendix 2 for details).

Daily Dose Pack Carton Labels

These revised carton labels were reviewed and found to be satisfactory (see Appendix 3 for details).

Sachet and Carton Labels

These labels were reviewed and found to be satisfactory (see Appendixes 4, 5, 6, and 7 for details).

Summary:

The draft labels that were submitted on January 18, 2020, are in compliance with National Drug Code, Bar Code and Product Identifier regulations, 21 CFR 201.25 & 21 CFR 207.35 (3)(i), 21 CFR 207.35, Subpart G – Labeling Standards 21 CFR 610.60 (a)(1) through (7) and 21 CFR 610.60 (7) (b) through (e), 21 CFR 610.62 (a) through (c), 21 CFR 610.63, 21 CFR 610.64, 21 CFR 610.67 and the Drug Supply Chain Security Act (DSCSA) and can be approved.

Daphne D. Stewart

APPENDIX 1

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICES FOOD AND DRUG ADMINISTRATION CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LABEL REVIEW – PACKAGE (appendix 1)	
STN &/or Reference Number known (if applies) STN 125696/0	
Product: Peanut [<i>Arachis hypogaea</i>] Allergen Powder - Palforzia® Initial Day Escalation (IDE) Carton 0.5 mg (1x0.5 mg white capsule), 1 mg (1x1 mg red capsule), 1.5 mg (1x0.5 mg white capsule, and 1x1 mg red capsule), 3 mg (3x1 mg red capsules), 6 mg (6x1 mg red capsules)	
Product Sponsor: Aimmune Therapeutics, Inc.	
Checked items indicate compliance	
21 CFR 610.61 (a)(1) through (7)	
a. Proper Name: position and prominence	X
b. Sponsor Name, address, license number	X
c. Lot Number	X
d. Expiration Date	X
e. Preservative	X
f. Number of containers	X
g. Amount of product	X
h. Storage temperature	X
i. Dose	X
j. Route of administration	X
k. Inactive ingredients	X
l. Source	X
m. Potency	X
n. "Rx Only"	X
o. Divided Sponsor	-
p. Distributor	-
q. Reference to package insert	x
JA 900.08: NDC, Bar Code, & Product Identifiers/21 CFR 201.25 & 21 CFR 207.35 (3)(i)	
18. Barcode & NDC a. Using the website (b) (4) (to check the sponsor's NDC) b. Click "Report" c. Click "NDC Labeler Code" d. Click "Toggle Parameters" e. Type in the first segment of the NDC then Click "Previous" The following information is shown for the sponsor NDC Labeler Code #, DUNS #, Firm Name, Effective Time, Document, Contact Name, Contact Email & Submission Time i. If you click on "Link" under Document – it will give you the sponsor's contact information, address, telephone # and email address	

<p>10. Detachable Portion</p> <p>If the detachable label has a 2D Barcode, then you need to follow steps #8 & steps #9 (Barcode & NDC/2D Barcode)</p> <p>The actual detach label needs to include:</p> <ul style="list-style-type: none"> a. Proprietary Name b. NDC # c. Lot # & Expiry Date <p>If the detachable label cannot contain all the above information, then it should have:</p> <ul style="list-style-type: none"> a. Proprietary Name b. NDC # c. Lot # <p>For 2D Barcodes on the carton label to meet the regulations for the Drug Supply Chain Security Act (DSCSA).</p> <p>The sponsor will need to indicate the affix of a 2D barcode and the Datamatrix code will need to be placed on the label. It should include:</p> <ul style="list-style-type: none"> a. GTIN # b. Lot # c. Exp # d. S/N # 	<p>x</p> <p>x</p> <p>x</p> <p>x</p> <p>x</p>
<p><u>11. If there is an age range associated with the label is should be included on the label. The placement should not be on the detachable portion</u></p>	

<p>Comments:</p> <ul style="list-style-type: none"> • This label is satisfactory for approval.

APPENDIX 2

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICES FOOD AND DRUG ADMINISTRATION CENTER FOR BIOLOGICS EVALUATION AND RESEARCH	
LABEL REVIEW – PACKAGE (appendix 2)	
STN &/or Reference Number known (if applies) STN 125696/0	
Product Peanut [<i>Arachis hypogaea</i>] Allergen Powder - Palforzia® Individual Blister (Physician Samples) 3 mg (NDC 71881-101-09), 6 mg (NDC 71881-101-09), 12 mg (NDC 71881-101-09), 20 g (NDC 71881-101-09), 40 mg (NDC 71881-101-09), 80 mg (NDC 71881-101-09), 120 mg (NDC 71881-101-09), 160 mg (NDC 71881-101-09), 200 mg (NDC 71881-101-09), 240 mg (NDC 71881-101-09)	
Product Sponsor: Aimmune Therapeutics, Inc.	
Checked items indicate compliance	
21 CFR 610.61 (a)(1) through (7)	
b. Proper Name: position and prominence	*see comments section
b. Sponsor Name, address, license number	X
c. Lot Number	X
d. Expiration Date	X
e. Preservative	X
f. Number of containers	X
g. Amount of product	X
h. Storage temperature	X
i. Dose	X
j. Route of administration	X
k. Inactive ingredients	X
l. Source	X
m. Potency	X
n. “Rx Only”	X
o. Divided Sponsor	-
p. Distributor	-
q. Reference to package insert	x
JA 900.08: NDC, Bar Code, & Product Identifiers/21 CFR 201.25, 21 CFR 203.3(i) & 21 CFR 207.35 (3)(i)	
Definition – Drug Samples <ul style="list-style-type: none"> means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug. 	X

<p>18. Barcode & NDC</p> <ol style="list-style-type: none"> Using the website (b) (4) (to check the sponsor's NDC) Click "Report" Click "NDC Labeler Code" Click "Toggle Parameters" Type in the first segment of the NDC then Click "Previous" <p>The following information is shown for the sponsor NDC Labeler Code #, DUNS #, Firm Name, Effective Time, Document, Contact Name, Contact Email & Submission Time</p> <ol style="list-style-type: none"> If you click on "Link" under Document – it will give you the sponsor's contact information, address, telephone # and email address 	
<p>10. Detachable Portion</p> <p>If the detachable label has a 2D Barcode, then you need to follow steps #8 & steps #9 (Barcode & NDC/2D Barcode)</p> <p>The actual detach label needs to include:</p> <ol style="list-style-type: none"> Proprietary Name NDC # Lot # & Expiry Date <p>If the detachable label cannot contain all the above information, then it should have:</p> <ol style="list-style-type: none"> Proprietary Name NDC # Lot # <p>For 2D Barcodes on the carton label to meet the regulations for the Drug Supply Chain Security Act (DSCSA).</p> <ol style="list-style-type: none"> Transaction under (581(24)(B)(v)) as well as the linear barcodes (21 CFR 201.25(b)(i)(A)). <p>The sponsor will need to indicate the affix of a 2D barcode and the Datamatrix code will need to be placed on the label. It should include:</p> <ol style="list-style-type: none"> GTIN # Lot # Exp # S/N # 	<p>x</p>
<p><u>11. If there is an age range associated with the label is should be included on the label. The placement should not be on the detachable portion</u></p>	

Comments:

- These labels are exempt from the JA: 900.08 National Drug Code, Bar Code and Product Identifier, 21 CFR 201.25(b) & 21 CFR 207.35 (3)(i) Product Identifier. This involves 2D barcode, 2D DataMatrix Code that consists of a Global Trade Item Number, Expiration Date, Lot Number, Serialization Number.
- These labels are under REMS review and do the requirements for samples labels under 21 CFR 203.3(i).
- These labels are satisfactory for approval.

APPENDIX 3

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICES FOOD AND DRUG ADMINISTRATION CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LABEL REVIEW – PACKAGE (appendix 3)	
STN &/or Reference Number known (if applies) STN 125696/0	
Product Peanut [<i>Arachis hypogaea</i>] Allergen Powder - Palforzia® Daily Dose Pack Packages 3 mg (NDC 71881-101-45), 6 mg (NDC 71881-102-09), 12 mg (NDC 71881-103-09), 21 g (NDC 71881-104-09), 40 mg (NDC 71881-105-09), 80 mg (NDC 71881-106-09), 120 mg (NDC 71881-107-09), 160 mg (NDC 71881-108-09), 200 mg (NDC 71881-109-09), 240 mg (NDC 71881-110-09)	
Product Sponsor: Aimmune Therapeutics, Inc.	
Checked items indicate compliance	
21 CFR 610.61 (a)(1) through (7)	
c. Proper Name: position and prominence	*see comments section
b. Sponsor Name, address, license number	X
c. Lot Number	X
d. Expiration Date	X
e. Preservative	X
f. Number of containers	X
g. Amount of product	X
h. Storage temperature	X
i. Dose	X
j. Route of administration	X
k. Inactive ingredients	X
l. Source	X
m. Potency	X
n. "Rx Only"	X
o. Divided Sponsor	-
p. Distributor	-
q. Reference to package insert	x
JA 900.08: NDC, Bar Code, & Product Identifiers/21 CFR 201.25 & 21 CFR 207.35 (3)(i)	
18. Barcode & NDC a. Using the website (b) (4) (to check the sponsor's NDC) b. Click "Report" c. Click "NDC Labeler Code" d. Click "Toggle Parameters" e. Type in the first segment of the NDC then Click "Previous" The following information is shown for the sponsor NDC Labeler Code #, DUNS #, Firm Name, Effective Time, Document, Contact Name, Contact Email & Submission Time i. If you click on "Link" under Document – it will give you the sponsor's contact information, address, telephone # and email address	

2 – Label Review – Package (**appendix 3**)

<p>10. Detachable Portion</p> <p>If the detachable label has a 2D Barcode, then you need to follow steps #8 & steps #9 (Barcode & NDC/2D Barcode)</p> <p>The actual detach label needs to include:</p> <ol style="list-style-type: none"> Proprietary Name NDC # Lot # & Expiry Date <p>If the detachable label cannot contain all the above information, then it should have:</p> <ol style="list-style-type: none"> Proprietary Name NDC # Lot # <p>For 2D Barcodes on the carton label to meet the regulations for the Drug Supply Chain Security Act (DSCSA).</p> <p>The sponsor will need to indicate the affix of a 2D barcode and the Datamatrix code will need to be placed on the label. It should include:</p> <ol style="list-style-type: none"> GTIN # Lot # Exp # S/N # 	<p>X</p> <p>X</p> <p>X</p> <p>X</p>
<p><u>11. If there is an age range associated with the label is should be included on the label. The placement should not be on the detachable portion</u></p>	

<p>Comments:</p> <ul style="list-style-type: none"> These labels are satisfactory for approval.
--

APPENDIX 4

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICES FOOD AND DRUG ADMINISTRATION CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LABEL REVIEW – CONTAINER (appendix 4)	
STN &/or Reference Number known (if applies): STN 125696/0	
Product: Peanut [<i>Arachis hypogaea</i>] Allergen Powder - - Palforzia® Sachet Container – 15 count 300 mg Sachet (Physician Sample) Container Label (National Drug Code 71881-111-09)	
Product Sponsor: Aimmune Therapeutics, Inc.	
Checked items indicate compliance	
21 CFR 610.60 (a)(1) through (7)	
* 1. Proper Name	X
* 2. Sponsor Name, address, license number	X
* 3. Lot Number	X
* 4. Expiration Date	X
* 5. Dose	X
* 6. “Rx Only”	X
7. Medication Guide	X
21 CFR 610.60 (7) (b) through (e)	
b. Package label information	-
c. Partial label	-
d. No container label	-
e. Visual inspection	X
JA 900.08: NDC, Bar Code, & Product Identifiers/21 CFR 201.25, 21 CFR 203.3)i) & 21 CFR 207.35 (3)(i)	
*8. Barcode Linear or One-Dimensional (1D) (Parallel Lines) 1. Transaction under (581(24)(B)(v)) as well as the linear barcodes (21 CFR 201.25(b)(i)(A)) NDC a. Using the website https://www.fda.gov/industry/structured-product-labeling-resources/ndcnhrlic-labeler-codes (to check the sponsor’s NDC) b. Click “Open” c. Click “ndc_nhrlic_labeler_codes” d. Click “Yes” e. Locate the Firm Name and the NDC Labeler Code will be to the right	X X X X X
Definition – Drug Samples means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.	X

<p>*9. Product Identifier - 2D Barcode</p> <p>a. Locate the symbol and the datamatrix code information will consist of: GTIN (01): EXPIRY (17): BATCH/LOT (10):</p>	-
<p>10. Detachable Portion</p> <p>If the detachable label has a 2D Barcode, then you need to follow steps #8 & steps #9 (Barcode & NDC/2D Barcode) The actual detach label needs to include:</p> <p>a. Proprietary Name b. NDC # c. Lot # & Expiry Date</p> <p>If the detachable label cannot contain all the above information, then it should have:</p> <p>a. Proprietary Name b. NDC # c. Lot #</p>	- - -
<p><u>11. If there is an age range associated with the label is should be included on the label. The placement should not be on the detachable portion</u></p>	
<p>Comments:</p> <ul style="list-style-type: none"> • These labels are exempt from the JA: 900.08 National Drug Code, Bar Code and Product Identifier, 21 CFR 201.25(b) & 21 CFR 207.35 (3)(i) Product Identifier. This involves 2D barcode, 2D DataMatrix Code that consists of a Global Trade Item Number, Expiration Date, Lot Number, Serialization Number. . • These labels are under REMS review and do the requirements for samples labels under 21 CFR 203.3(i). • These labels are satisfactory for approval. 	

*** Minimum requirement for partial labels**

APPENDIX 5

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICES FOOD AND DRUG ADMINISTRATION CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LABEL REVIEW – PACKAGE (appendix 5)	
STN &/or Reference Number known (if applies): STN 125696/0	
Product: Peanut [<i>Arachis hypogaea</i>] Allergen Powder - - Palforzia® Sachet Carton – 15 count 300 mg Sachet (Physician Sample) Package Label (National Drug Code 71881-111-99)	
Product Sponsor: Aimmune Therapeutics, Inc.	
Checked items indicate compliance	
21 CFR 610.61 (a)(1) through (7)	
a. Proper Name: position and prominence	x
b. Sponsor Name, address, license number	x
c. Lot Number	x
d. Expiration Date	x
e. Preservative	x
f. Number of containers	x
g. Amount of product	X
h. Storage temperature	X
i. Dose	X
j. Route of administration	X
k. Inactive ingredients	X
l. Source	X
m. Potency	X
n. “Rx Only”	X
o. Divided Sponsor	-
p. Distributor	X
q. Reference to package insert	x
JA 900.08: NDC, Bar Code, & Product Identifiers/21 CFR 201.25 & 21 CFR 207.35 (3)(i)	
18. Barcode & Linear or One-Dimensional (1D) (Parallel Lines)	
NDC	x
a. Using the website https://www.fda.gov/industry/structured-product-labeling-resources/ndcnhrlic-labeler-codes (to check the sponsor’s NDC)	x
b. Click “Open”	x
c. Click “ndc_hric_labeler_codes”	x
d. Click “Yes”	
e. Locate the Firm Name and the NDC Labeler Code will be to the right	
Definition – Drug Samples means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.	x

<p>10. Detachable Portion</p> <p>If the detachable label has a 2D Barcode, then you need to follow steps #8 & steps #9 (Barcode & NDC/2D Barcode)</p> <p>The actual detach label needs to include:</p> <ol style="list-style-type: none"> Proprietary Name NDC # Lot # & Expiry Date 	
<p>If the detachable label cannot contain all the above information, then it should have:</p> <ol style="list-style-type: none"> Proprietary Name NDC # Lot # <p>For 2D Barcodes on the carton label to meet the regulations for the Drug Supply Chain Security Act (DSCSA).</p> <ol style="list-style-type: none"> Transaction under (581(24)(B)(v)) as well as the linear barcodes (21 CFR 201.25(b)(i)(A)) <p>The sponsor will need to indicate the affix of a 2D barcode and the Datamatrix code will need to be placed on the label. It should include:</p> <ol style="list-style-type: none"> GTIN # Lot # Exp # S/N # 	<p>x</p>
<p><u>11. If there is an age range associated with the label is should be included on the label. The placement should not be on the detachable portion</u></p>	
<p>Comments:</p> <ul style="list-style-type: none"> These labels are exempt from the JA: 900.08 National Drug Code, Bar Code and Product Identifier, 21 CFR 201.25(b) & 21 CFR 207.35 (3)(i) Product Identifier. This involves 2D barcode, 2D DataMatrix Code that consists of a Global Trade Item Number, Expiration Date, Lot Number, Serialization Number. These labels are under REMS review and do meet the requirements for samples labels under 21 CFR 203.3(i). These labels are satisfactory for approval. 	

APPENDIX 6

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICES FOOD AND DRUG ADMINISTRATION CENTER FOR BIOLOGICS EVALUATION AND RESEARCH	
LABEL REVIEW – CONTAINER (appendix 6)	
STN &/or Reference Number known (if applies): STN 125696/0	
Product: Peanut [<i>Arachis hypogaea</i>] Allergen Powder - – Palforzia® Sachet Container – 15 count 300 mg Sachet (Up-Dosing and Maintenance) Container Label (National Drug Code 71881-111-01)	
Product Sponsor: Aimmune Therapeutics, Inc.	
Checked items indicate compliance	
21 CFR 610.60 (a)(1) through (7)	
* 1. Proper Name	(see comments section)
* 2. Sponsor Name, address, license number	x
* 3. Lot Number	x
* 4. Expiration Date	x
* 5. Dose	x
* 6. “Rx Only”	x
7. Medication Guide	x
21 CFR 610.60 (7) (b) through (e)	
b. Package label information	-
c. Partial label	-
d. No container label	-
e. Visual inspection	X
JA 900.08: NDC, Bar Code, & Product Identifiers/21 CFR 201.25 & 21 CFR 207.35 (3)(i)	
*8. Barcode Linear or One-Dimensional (1D) (Parallel Lines) NDC a. Using the website https://www.fda.gov/industry/structured-product-labeling-resources/ndcnhric-labeler-codes (to check the sponsor’s NDC) b. Click “Open” c. Click “ndc_nhric_labeler_codes” d. Click “Yes” e. Locate the Firm Name and the NDC Labeler Code will be to the right	X X X X X

<p>*9. Product Identifier - 2D Barcode</p> <p>a. Locate the symbol and the datamatrix code information will consist of:</p> <p>GTIN (01):</p> <p>EXPIRY (17):</p> <p>BATCH/LOT (10):</p>	<p>(see comments section)</p>
<p>10. Detachable Portion</p> <p>If the detachable label has a 2D Barcode, then you need to follow steps #8 & steps #9 (Barcode & NDC/2D Barcode)</p> <p>The actual detach label needs to include:</p> <p>a. Proprietary Name</p> <p>b. NDC #</p> <p>c. Lot # & Expiry Date</p> <p>If the detachable label cannot contain all the above information, then it should have:</p> <p>a. Proprietary Name</p> <p>b. NDC #</p> <p>c. Lot #</p>	<p>-</p> <p>-</p> <p>-</p>
<p><u>11. If there is an age range associated with the label is should be included on the label. The placement should not be on the detachable portion</u></p>	
<p>Comments:</p> <ul style="list-style-type: none"> This label is satisfactory for approval. 	

*** Minimum requirement for partial labels**

APPENDIX 7

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICES FOOD AND DRUG ADMINISTRATION CENTER FOR BIOLOGICS EVALUATION AND RESEARCH	
LABEL REVIEW – PACKAGE (appendix 7)	
STN &/or Reference Number known (if applies): STN 125696/0	
Product: Peanut [<i>Arachis hypogaea</i>] Allergen Powder - - Palforzia® Sachet Carton – 15 count 300 mg Sachet – 15 count Package Label (National Drug Code 71881-111-15)	
Product Sponsor: Aimmune Therapeutics, Inc.	
Checked items indicate compliance	
21 CFR 610.61 (a)(1) through (7)	
a. Proper Name: position and prominence	(see comments section)
b. Sponsor Name, address, license number	x
c. Lot Number	x
d. Expiration Date	x
e. Preservative	x
f. Number of containers	x
g. Amount of product	X
h. Storage temperature	X
i. Dose	X
j. Route of administration	X
k. Inactive ingredients	X
l. Source	X
m. Potency	X
n. “Rx Only”	X
o. Divided Sponsor	-
p. Distributor	X
q. Reference to package insert	x
JA 900.08: NDC, Bar Code, & Product Identifiers/21 CFR 201.25 & 21 CFR 207.35 (3)(i)	
18. Barcode & Linear or One-Dimensional (1D) (Parallel Lines)	x
NDC	x
a. Using the website https://www.fda.gov/industry/structured-product-labeling-resources/ndcnhric-labeler-codes (to check the sponsor’s NDC)	x
b. Click “Open”	x
c. Click “ndc_hric_labeler_codes”	x
d. Click “Yes”	x
e. Locate the Firm Name and the NDC Labeler Code will be to the right	

<p>10. Detachable Portion</p> <p>If the detachable label has a 2D Barcode, then you need to follow steps #8 & steps #9 (Barcode & NDC/2D Barcode)</p> <p>The actual detach label needs to include:</p> <ul style="list-style-type: none"> a. Proprietary Name b. NDC # c. Lot # & Expiry Date 	
<p>If the detachable label cannot contain all the above information, then it should have:</p> <ul style="list-style-type: none"> a. Proprietary Name b. NDC # c. Lot # <p>For 2D Barcodes on the carton label to meet the regulations for the Drug Supply Chain Security Act (DSCSA).</p> <p>The sponsor will need to indicate the affix of a 2D barcode and the Datamatrix code will need to be placed on the label. It should include:</p> <ul style="list-style-type: none"> q. GTIN # r. Lot # s. Exp # t. S/N # 	
<p><u>11. If there is an age range associated with the label is should be included on the label. The placement should not be on the detachable portion</u></p>	
<p>Comments:</p> <ul style="list-style-type: none"> • This label is satisfactory for approval. 	