



U.S. FOOD & DRUG
ADMINISTRATION

DATE: 31 January 2020

TO: File: 125696

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Laboratory of Immunobiochemistry (LIB) /DBPAP/OVRR/CBER

THROUGH: Ronald L. Rabin, MD
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PRODUCT: Palforzia, Peanut (*Arachis hypogaea*) Allergen Powder-dnfp

SUBJECT: Module 3 update plans

APPLICANT: Aimmune

During review of this original BLA Aimmune submitted multiple responses to CMC Information Requests into Module 1 of the eCTD. Much of the information contained in recent CMC IRs should also have been updated in Module 3, but was not. This information includes current protocols, specifications, procedures and data from batch release and stability testing. In a telecon on 28 January 2020, we discussed this with Aimmune. After the telecon, they reviewed the eCTD files and stated that due to all the hyperlinks between all the documents, it is only feasible to update all documents together and that this would take several weeks.

In an amendment to the BLA received on 31 January 2020, Aimmune provided a summary document of all the documents that need updating (See Table 1. Below). Aimmune acknowledges that this document is not intended to be comprehensive but includes the sections and major points that will be addressed during the updates. The list of documents to be updated appears to cover all the information provided in recent amendments that should be submitted to Module 3, but we acknowledge that there may be additional documents or points identified for updating during the process.

Table 1. Summary of quality modules requiring updates

Section	Rationale for changes
2.3.S	Overall summaries require updates consistent with updates to the quality modules. 2.3.R needs comparability protocol removed.
2.3.P	Overall summaries require updates consistent with updates to the quality modules. 2.3.R needs comparability protocol removed.
2.3.R	Overall summaries require updates consistent with updates to the quality modules. 2.3.R needs comparability protocol removed.

Section	Rationale for changes
3.2.S.1.1	Update nomenclature to include Palforzia and the dnfp suffix
3.2.S.2.1	According to the information described in SN0071
3.2.S.2.3	Updates to source material lot selection process
3.2.S.6	Diagrams of (b) (4) to be added
3.2.S.4.1	Specifications to be updated
3.2.S.4.3	(b) (4) validation data to be updated with additional validation results
3.2.S.4.4	Batch analysis updated to capture recent batches used in specification setting
3.2.S.4.5	Justification of specifications updated with revised tolerance intervals
3.2.S.5	Reference standard specifications and other details updated
3.2.S.7.1	Updated stability summary
3.2.S.7.3	Updates to stability data
3.2.P.1	NDC numbers for capsules to be added
3.2.P.3.1	According to the information described in SN0071
3.2.P.3.3	Blending (b) (4) (SN0030, comment 1b)
3.2.P.3.4	(b) (4) specifications to be updated
3.2.P.5.1	Specifications to be updated
3.2.P.5.4	Batch analysis with release commercial batches used in specification setting
3.2.P.5.6	Justification of specifications to be updated with revised tolerance intervals
3.2.P.8.1	Updates to stability summary and proposed shelf-life
3.2.P.8.2	Updated stability commitment regarding 300 mg sachet per SN0082
3.2.P.8.3	Stability data, data tables, and data analysis updated
3.2.R.2	Critical reagent information (antibodies, reference standards)
3.2.R.3	Comparability protocol removed from Module 3