



U.S. FOOD & DRUG
ADMINISTRATION

Memorandum

DATE: October 21, 2019

FROM: Erin McDowell, Bioresearch Monitoring Branch
Division of Inspections and Surveillance
Office of Compliance and Biologics Quality

THROUGH: Dennis Cato, Branch Chief, Bioresearch Monitoring Branch

Carrie M. Mampilly, M.P.H., Director, Division of Inspections and Surveillance

TO: Taruna Khurana, Ph.D., Chair/Primary Reviewer
Kathleen Hise, M.D., Clinical Reviewer
Diana Oram, Ph.D., RPM
Qun Wang, Ph.D., RPM
Tatiana Claro da Silva, Ph.D., RPM

SUBJECT: Bioresearch Monitoring Review Memo
APPLICANT: Aimmune Therapeutics, Inc.
PRODUCT: AR101 Peanut Allergen Powder
BLA: 125696/0

Review Summary

Bioresearch Monitoring (BIMO) inspections were conducted at six clinical investigator (CI) Sites that participated in the conduct of Study ARC003 with four of the sites additionally conducting Study ARC007. Data from one study site, Site 009 does not appear to be reliable or contemporaneous and may not be suitable for inclusion in the analysis for this application. The inspections of the other CI sites did not reveal significant problems that impact the data submitted in the Biologics License Application (BLA).

Background

Aimmune Therapeutics, Inc. submitted this BLA to obtain marketing approval to reduce the risk of anaphylaxis after accidental exposure to peanuts. The following studies were conducted to support this BLA.

ARC003: Peanut Allergy Oral Immunotherapy Study of AR101 for Desensitization in Children and Adults (PALISADE)

ARC007: Real-World AR101 Market-Supporting Experience Study in Peanut-Allergic Children Ages 4 to 17 Years (RAMSES)

Studies ARC003 and ARC007 were conducted at 46 and 62 sites, respectively. Five domestic and one foreign CI sites were inspected in support of this BLA, representing 14% of the subjects enrolled in ARC003 and 10% of the subjects enrolled in ARC007. The sites were selected based on previous inspectional history and geographic location. The inspection was performed in accordance with FDA's Compliance Program Guidance Manual (CPGM) 7348.811, Inspection Program for Clinical Investigators. The inspection assignment included specific questions concerning the study protocol and information submitted in the BLA was compared to source documents at the study sites.

Inspectional Findings

The table below summarizes the BIMO inspections.

Site ID	Study Inspected	Study Site	Location	483 Issued	Final Inspection Classification
001	Studies ARC003 and ARC007	Cincinnati Children's Hospital Medical Center	Cincinnati, Ohio	No	No Action Indicated
009	Studies ARC003 and ARC007	Baker Allergy, Asthma, and Dermatology Research Center, LLC	Portland, Oregon	No	No Action Indicated
021	Study ARC003	Colorado Allergy & Asthma Centers, PC	Centennial, Colorado	No	No Action Indicated
023	Studies ARC003 and ARC007	UCLA Medical Center, Santa Monica	Santa Monica, California	No	No Action Indicated
039	Studies ARC003 and ARC007	Atlanta Allergy & Asthma Clinic, PA	Marietta, Georgia	No	No Action Indicated
105	Study ARC003	Universitätsklinikum Frankfurt	Frankfurt, Germany	No	No Action Indicated

The inspection at Sites 001, 021, 023, 039, and 105 did not reveal significant findings related to the conduct of the study. BIMO notes that the clinical investigator, Dr. James Baker, at Site 009 was disqualified May 2018. Data from Dr. Baker's site does not appear to be reliable or contemporaneous and may not be suitable for inclusion in the safety and/or efficacy analysis for this application. The inspection at Site 009 revealed adverse events were not documented as reviewed and evaluated, and there were discrepancies between the source documents and the electronic case report forms for the kit numbers used for two doses.

Sponsor/Monitoring Issues

No sponsor or monitoring issues were identified during the clinical site inspections.

Financial Disclosure

The CI Compliance Program directs the FDA investigator to ask the CI if and when he/she disclosed information about his/her financial interests to the sponsor and/or interests of any sub-investigators, spouse(s) and dependent children, including if and when the information was updated. The information submitted to the BLA was verified for each of the inspected CI sites.

Administrative Follow-up:

Information letters were issued to the CI at each of the inspected study sites. Should you have any questions or comments about the contents of this memo or any aspect of BIMO, please contact me at 240-402-9014.

Erin McDowell
Consumer Safety Officer

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