

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER		DATE(S) OF INSPECTION
7520 Standish Place (HFD-45) Rockville, MD 20855-2773 (301) 594-0020 Fax: (301) 594-1204		9/4/2023-9/15/2023*
		FEI NUMBER
		3010031951
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED		
Kyung-Ah Kim, Executive Vice President, Head of Development Division		
FIRM NAME	STREET ADDRESS	
Samsung Bioepis Co., Ltd.	76 Songdogyoyuk -Ro	
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED	
Yeonsu, INCHEON, 21987 Korea (the Republic of)	Sponsor and PADE	

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

Sponsor Inspection of Samsung Bioepis Co., Ltd., (b) (4) Study (b) (4)

OBSERVATION 1

Failure to ensure proper monitoring of the study, ensure the study is conducted in accordance with the protocol and/or investigational plan and ensure that FDA and all investigators are promptly informed of significant new adverse effects or risks.

Specifically,

- A. The death of subject (b) (6) from study (b) (4) was not promptly reported and communicated to the Agency (FDA). The death of subject (b) (6) was identified by the clinical investigator and study staff for site (b) (4) on (b) (6). The outcome of the event was reported to be fatal (Grade 5 in severity). As identified in the audit trail of the electronic Case Report Form (eCRF), the fatal event was not reported to the Sponsor until 09 Mar 2020.
- B. Section 12 of the Monitoring Plan, states that "Queries resolution timelines are (b) (4). Review of the clinical monitoring query reports identified one hundred eighty-seven (187) queries taking twenty (20) days or more to be resolved. Out of these one hundred eighty-seven (187) queries, thirty-three (33) took fifty (50) days or longer to reach resolution, with the longest closure time for a query being four hundred forty-five (445) days.

PADE Inspection of Samsung Bioepis Co. Ltd., (b) (4) (b) (4)

OBSERVATION 2

Failure to submit each post marketing 15-day alert and post marketing 15-day alert follow up report as required.

Specifically,

The review of expedited 15-day alert report identified sixteen (16) Serious and Unexpected Adverse Events cases that were incorrectly processed, leading to reports exceeding the 15-day reporting timeframe. Fifteen (15) out of sixteen (16) cases as seen in the table below were more than forty (40) days late.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Scott N Lim, Consumer Safety Officer	
<div style="text-align: right; margin-right: 20px;"> Scott N Lim Consumer Safety Officer Signed By: 202619245 Date Signed: 09-15-2023 09:34:48 <hr/> X </div>		

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Case ID	Latest Received Date	IQVIA Case Processing Team Received Date	Due date of Submission	Date submitted to FDA	Delta (LRD to Submission)
(b) (6)	12/23/2020	12/23/2023	1/7/2021	2/1/2021	40
	1/29/2021	12/1/2021	12/14/2021	1/27/2022	59
	4/6/2022	4/7/2022	4/21/2022	6/1/2022	56
	4/25/2022	4/26/2023	5/10/2022	9/8/2023	501
	5/3/2022	5/4/2022	5/18/2022	2/9/2023	282
	5/10/2022	8/11/2022	8/25/2022	10/7/2022	58
	5/10/2022	8/11/2022	8/25/2022	2/9/2023	183
	5/30/2022	8/31/2022	9/14/2022	9/1/2023	367
	9/28/2022	9/29/2022	10/13/2022	11/30/2022	63
	10/27/2022	10/27/2022	11/11/2022	1/4/2023	69
	10/29/2022	10/31/2022	11/13/2022	11/16/2022	18
	12/20/2022	12/21/2022	1/4/2023	2/9/2023	51
	3/15/2023	3/16/2023	3/30/2023	5/12/2023	58
	3/15/2023	3/16/2023	3/30/2023	4/26/2023	42
	5/30/2023	6/30/2023	7/15/2023	8/18/2023	49
	5/29/2023	6/30/2023	7/14/2023	8/18/2023	50

***DATES OF INSPECTION**

9/04/2023(Mon), 9/05/2023(Tue), 9/06/2023(Wed), 9/07/2023(Thu), 9/08/2023(Fri), 9/11/2023(Mon), 9/12/2023(Tue), 9/13/2023(Wed), 9/14/2023(Thu), 9/15/2023(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Scott N Lim, Consumer Safety Officer	
	<p align="center">X</p> <p>Scott N Lim Consumer Safety Officer Signed By: 202619245 Date Signed: 09-15-2023 09:34:48</p>	