

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

Before the Honorable Clark S. Cheney
Administrative Law Judge

In the Matter of

**CERTAIN PRE-FILLED SYRINGES
FOR INTRAVITREAL INJECTION AND
COMPONENTS THEREOF**

Investigation No. 337-TA-1207

DECLARATION OF RAYNA VENOOK

I, **Rayna Venook**, state and declare as follows:

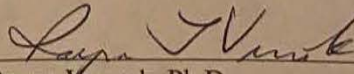
1. I am presently employed as a Global Team Lead in Regulatory Information Management at Genentech, Inc. ("Genentech") in South San Francisco, California where, among other things, I am involved in managing information and data associated with Genentech's regulatory submissions.
2. I am over the age of 18, of sound mind, and capable of making this declaration. I am submitting this declaration based on my own knowledge, personal experience, and my duties within the ordinary course of business at Genentech. If called upon, I can competently testify to the facts stated in this declaration.
3. Genentech uses a database called the Global Product Regulatory System ("GPRS") to store materials relating to its products, including electronic copies of regulatory submissions to the United States Food and Drug Administration ("FDA"). In the normal course of Genentech's business, members of my group oversee and manage the process by which true and accurate copies of FDA submissions are archived to the GPRS following transmission to the agency.
4. According to Genentech's standard practice, Supplemental Biologics License Application ("sBLA") number 125156/S-110 was archived in GPRS on June 17, 2016 and 125156/S-117 was archived in GPRS on November 21, 2017.
5. I understand that copies of Sections 3.2.P.3.3; 3.2.P.3.5; 3.2.P.3.5.1; 3.2.P.7; 3.2.R; and 3.2.A.1(Fruh), (Sterigenics), and (Vetter) from the Chemistry, Manufacturing, and Controls portions of sBLA 125156/S-110 and 125156/S-117 have been produced bearing the following Bates labels:

BLA 125156/S-110	
3.2.P.3.3	GENEITC_1207-0003675 - GENEITC_1207-0003682
3.2.P.3.5	GENEITC_1207-0003704 - GENEITC_1207-0003737
3.2.P.3.5.1	GENEITC_1207-0003683 - GENEITC_1207-0003703
3.2.P.7	GENEITC_1207-0003545 - GENEITC_1207-0003550
3.2.R	GENEITC_1207-0003551 - GENEITC_1207-0003630
3.2.A.1 (Vetter)	GENEITC_1207-0003652 - GENEITC_1207-0003674
3.2.A.1 (Sterigenics)	GENEITC_1207-0003644 - GENEITC_1207-0003651
3.2.A.1 (Fruh)	GENEITC_1207-0003631 - GENEITC_1207-0003643
BLA 125156/S-117	
3.2.P.3.3	GENEITC_1207-0003481 - GENEITC_1207-0003488
3.2.P.3.5	GENEITC_1207-0003503 - GENEITC_1207-0003544
3.2.P.3.5.1	GENEITC_1207-0003489 - GENEITC_1207-0003502
3.2.P.7	GENEITC_1207-0003412 - GENEITC_1207-0003417
3.2.R	GENEITC_1207-0003418 - GENEITC_1207-0003457
3.2.A.1 (Vetter)	GENEITC_1207-0003468 - GENEITC_1207-0003480
3.2.A.1 (Sterigenics)	GENEITC_1207-0003464 - GENEITC_1207-0003467
3.2.A.1 (Fruh)	GENEITC_1207-0003458 - GENEITC_1207-0003463

6. The Bates-labeled documents listed above are true and correct copies of the corresponding sections of sBLA 125156/S-110 and 125156/S-117 maintained in GPRS.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 20 day of November, 2020 at Millbrae, California.


Rayna Venook, Ph.D.