UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

DIVISION OF
CORPORATION FINANCE

November 15, 2021

Robert Hershberg, M.D., Ph.D.
Chief Executive Officer
HilleVax, Inc.
75 State Street
Suite 100 - #9995
Boston, MA 02109

Re: HilleVax, Inc.
Draft Registration Statement on Form S-1
Submitted October 19, 2021
CIK No. 0001888012

Dear Dr. Hershberg:

We have reviewed your draft registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

Draft Registration Statement submitted on October 19, 2021

Overview, page 1

1. We note your disclosure that you plan to initiate a Phase 2b clinical trial for HIL-214. Please revise to disclose whether you will need to submit an investigational new drug application to the FDA before you can begin that trial and clarify when you intend to make such submission, if required. We also note your disclosure on page 117 that you have designed your planned Phase 2b clinical trial based on learnings from the NOR-211 Phase 2b study as well as preliminary feedback Takeda received from the FDA and European Medicines Agency. Given this disclosure, please also indicate, if true, that the FDA may not accept or view the clinical trial results from Takeda, other third parties, or non-U.S. regulators as sufficient to allow you to advance to a Phase 2b study and may require you to conduct additional trials before proceeding to a Phase 2b trial.

Summary, page 1

2. Please revise your disclosure to include a pipeline table illustrating your clinical development program for HIL-214.

3. Please balance your disclosure in the Summary to clarify that the nine clinical trials of HIL-214 to date have been conducted by Takeda and its predecessor, LigoCyte Pharmaceuticals, Inc., and that you have not yet completed any clinical trials or submitted an IND or its equivalent to the applicable regulatory agencies.

HIL-214 clinical data and development plan, page 4

4. We refer to your disclosure on page 4 that HIL-214's adverse event profile was observed to be similar to that of approved alum-adjuvanted vaccines. Please revise to expand your disclosure of any adverse events that were observed in the clinical trials in both infants and adults.

Commercial opportunity, page 5

5. We note your disclosure here and elsewhere in the registration statement that you believe that Shingrix, a vaccine developed to prevent shingles, is a market analogue for HIL-214 for purposes of estimating your market opportunity. In an appropriate location in your prospectus, please expand your discussion to support this statement.

Our team and investors, page 6

6. We note that you identify a group of "leading investors" in your company in this section, however, some of these investors do not appear to be among the principal stockholders that are identified on page 168. Please relocate this disclosure from your prospectus summary to your "Principal Stockholder" section. We note in this regard that the identification of the pre-IPO investors in your prospectus summary may appear to suggest that potential investors in your public offering consider investments made by the pre-IPO investors as a factor in making an investment decision without knowing, among other things, the amount of each pre-IPO investor's investment in total or on a per share basis, their investment strategies or whether those investors will continue to hold their shares in the future, as some of the pre-IPO investors may not be subject to the reporting requirements of Section 16 of the Exchange Act, and investors in your public offering will not necessarily know when some of the pre-IPO investors decide to sell any of their shares. In addition to relocating this disclosure, please limit any textual description of your pre-IPO investors in your "Principal Stockholders" section to the investors identified in that table.

Summary of risks related to our business, page 7

7. We refer to your disclosure on pages 37 and 119 that a key element of your commercial strategy is to receive advisory body recommendations for the use of HIL-214, particularly from the Advisory Committee on Immunization Practices (ACIP) of the CDC. Please include as a principal risk factor the risk to your business in the event your vaccine candidate is not recommended by ACIP.

Risk factors, page 14

8. We note your disclosure on page 156 that the administrator of the 2022 Plan may, without the approval of stockholders, amend any outstanding stock option or SAR to reduce its price per share, other than in the context of corporate transactions or equity restructurings. Please include appropriate risk factor disclosure, including whether proxy advisory firms could find such repricing without stockholder approval contrary to a performance-based pay philosophy.

We face significant competition..., page 39

9. We refer to your disclosure relating to your competitors who are also developing a vaccine for norovirus. Please disclose whether any of your competitors are also focused on developing a vaccine consisting of VLPs representing the GI and GII genogroups of norovirus. Please also disclose whether any of your competitors are also developing pediatric vaccines for the prevention of norovirus-related illness.

Our amended and restated certificate of incorporation and amended and restated bylaws..., page 74

10. We note your disclosure on page 74 that the forum selection in your amended and restated certificate of incorporation and bylaws may limit a shareholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with you and may discourage such lawsuits. Please revise this risk factor to disclose that there is also a risk that your forum selection provision may result in increased costs for investors to bring a claim.

Special note regarding forward-looking statements, page 80

11. We note your statement cautioning investors not to rely on forward-looking statements and projections in your prospectus. These statements may imply an inappropriate disclaimer of responsibility; therefore, please either remove the potential disclaiming language or clearly state in this section that you are liable for such information.

Use of proceeds, page 82

12. Please revise to disclose how far the proceeds you plan to allocate from the offering toward the clinical development of HIL-214 will allow you to proceed with such program. Refer to Instruction 3 to Item 504 of Regulation S-K.

Management's discussion and analysis of financial condition and results of operations
Critical accounting policies and significant judgments and estimates, page 98

13. Once you have an estimated offering price or range, please explain to us how you determined the fair value of the common stock underlying your equity issuances and the reasons for any differences between the recent valuations of your common stock leading up to the IPO and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances including stock compensation and beneficial conversion features. Please discuss with the staff how to submit your response.

Business, page 100

14. Please clarify the meaning of scientific or technical terms the first time they are used in order to ensure that all investors will understand the disclosure. For example, please briefly explain what you mean by bivalent, immunogenicity and seroresponse rates.

Dose finding and formulation trials in adults, page 112

15. We refer to your disclosure of the dose finding and formulation trials and efficacy trials conducted in adults starting on page 112. Please expand your disclosure of the scope and design of the trials, including the size of each trial and the type of placebo used, whether the dose finding trials were powered for statistical significance, whether any adverse side effects were observed and to discuss the data from the results to support the conclusions drawn concerning immunogenicity, as applicable.

Safety results in infants and children, page 115

16. We note your disclosure on pages 115 and 116 of the adverse events and reactions observed in infants, children and older adults in the NOR-202 and other clinical trials for HIL-214. Please revise to clarify the number of participants who experienced the adverse effects referenced.

Phase 2b infant efficacy trial, page 117

17. We note your disclosure that subjects in your planned Phase 2b infant efficacy trial will receive HIL-214 (50/150 µg GI.1/GII.4 VLP combination with 500 µg alum) in a two-dose regimen delivered 28 to 56 days apart and that you have designed your planned Phase 2b clinical trial based on learnings from the NOR-211 Phase 2b study as well as preliminary feedback Takeda received from the FDA and European Medicines Agency. We also note your disclosure on page 112 regarding the dosage and scheduling for infants in the NOR-202 trial. If your dosage and scheduling in your Phase 2b infant efficacy trial also will be based on data from NOR-202, please revise to make that clear and indicate the dosing schedule for infants in NOR-202.

Intellectual property, page 120

18. We note your disclosure relating to the nine patent families of your patent portfolio. Please clarify your disclosure to identify for each patent family the scope and technology of each such patent family or patent application, the type of patent protection (such as composition of matter, use or process), the applicable jurisdiction of the issued foreign patents and foreign pending patent applications and expiration years.

License agreement and clinical manufacturing and supply agreement, page 164

19. We note your disclosure that in connection with the Takeda License, you provided Takeda with various investor rights, including pre-emptive rights, drag along rights, voting rights and certain registration rights. Please clarify whether these rights will terminate upon the closing of your public offering.

Principal stockholders, page 168

20. In your revised prospectus, please identify in the footnote to your table the natural persons who are the beneficial owners of the shares held by Takeda Vaccines, Inc., as applicable.

Financial Statements, page F-1

21. Please revise to provide a description of your capital stock and disclose the terms of all common and preferred shares, warrants, etc. in the footnotes to your financial statements.

General

22. Please provide us with supplemental copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, have presented or expect to present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not you retained, or intend to retain, copies of those communications.

You may contact Julie Sherman at 202-551-3640 or Terence O'Brien at 202-551-3355 if you have questions regarding comments on the financial statements and related matters. Please contact Jane Park at 202-551-7439 or Tim Buchmiller at 202-551-3635 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Cheston J. Larson, Esq.