U.S. FOOD & DRUG ADMINISTRATION

Re: VYNDAMAX - NDA 212161
VYNDAQEL - NDA 211996
Patent Nos. 7,214,695; 7,214,696
Docket Nos. FDA-2022-E-3123
FDA-2022-E-3120

The Honorable Katherine K. Vidal
Under Secretary of Commerce for Intellectual Property
Director, United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

FEB 08 2024

Dear Director Vidal:

This letter is in response to the applications for patent term extension for U.S. Patent Nos. 7,214,695 and 7,214,696 filed by The Scripps Research Institute (SCRIPPS), under 35 U.S.C. 156. The human drug products claimed by the patents are VYNDAMAX (tafamidis), which was assigned new drug application (NDA) No. 212161 and VYNDAQEL (tafamidis meglumine), which was assigned NDA No. 211996.

A review of the Food and Drug Administration's official records indicates that each of these products was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. 156(a)(4).

USPTO has requested information about whether the FDA first approved VYNDAMAX (NDA 212161, tafamidis) or VYNDAQEL (NDA 211996, tafamidis meglumine). Our records indicate that the two NDAs were received for review at the same time and were approved concurrently in the same approval action. Consequently, because both applications were approved at the same time, both applications represent the first permitted commercial marketing or use of the product or the individual active ingredients, as outlined under 35 U.S.C. sections 156(a)(5) and 156(f)(1).

NDA 212161 and NDA 211996 were approved concurrently on May 3, 2019, at 6:13 pm, which makes the submission of the patent term extension applications on June 27, 2019, timely within the meaning of 35 U.S.C. 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the *Federal Register*, and notify you of our determination.

U.S. Food and Drug Administration
10903 New Hampshire Avenue
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Please let me know if we can be of further assistance.

Sincerely yours,

Patrizia Cavazzoni

Patrizia Cavazzoni, M.D., Director
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