

BLA Number: 125752
Holder: Moderna TX, Inc.
Subject: SPIKEVAX
RE: Letter of Cross-Reference

The following Table 1 describes the applications cross-referenced in this Biological License Application (BLA).

Type/Number/Holder	Title	Date
BB-IND-19365 Holder: Division of Microbiology and Infectious Diseases (DMID)	Human Coronavirus (2019-nCoV; Pre-fusion Spike Protein; Lipid Nanoparticles; messenger RNA-1273; ModernaTx, Inc.) Vaccine	Letter of Authorization to Cross-Reference received on 31Mar2020
IND 19745 Sponsor: ModernaTx., Inc	MRNA-1273, a messenger RNA (mRNA)-based active immunization to induce protective immunity against respiratory disease associated with the SARS-COV-2 virus	Non-Hold Letter Received on 06May2020
EUA 27073 Manufacturer: ModernaTx., Inc	Moderna COVID-19 Vaccine Suspension for injection	Approved for Emergency Use on 18Dec2020

Sincerely,

**Michelle
Olsen**

Digitally signed by
 Michelle Olsen
 Date: 2021.08.06 15:49:48
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Approval	Michelle Olsen Regulatory 06-Aug-2021 19:52:57 GMT+0000
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