



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

August 23, 2021

Christopher Nagra
BioNTech Manufacturing GmbH
7000 Portage Road
Kalamazoo, Michigan 49001

Report on action taken on product submitted:

Released

COVID-19 Vaccine, mRNA

Lot No(s).:
FD7220

Sincerely,

John A. Eltermann -S

Digitally signed by John A. Eltermann -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA,
ou=People, 0.9.2342.19200300.100.1.1=1300049305,
cn=John A. Eltermann -S
Date: 2021.08.23 09:41:21 -04'00'

For Peter Marks, MD, PhD
Director
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration

125742-0 /2229 /FC



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

August 23, 2021

Christopher Nagra
BioNTech Manufacturing GmbH
7000 Portage Road
Kalamazoo, Michigan 49001

Report on action taken on product submitted:

Released

COVID-19 Vaccine, mRNA

Lot No(s).:
FE3592

Sincerely,

John A. Eltermann -S

Digitally signed by John A. Eltermann -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA,
ou=People, 0.9.2342.19200300.100.1.1=1300049305,
cn=John A. Eltermann -S
Date: 2021.08.23 09:40:29 -04'00'

For Peter Marks, MD, PhD
Director
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration

125742-0 /2229 /FC



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

August 23, 2021

Christopher Nagra
BioNTech Manufacturing GmbH
7000 Portage Road
Kalamazoo, Michigan 49001

Report on action taken on product submitted:

Released

COVID-19 Vaccine, mRNA

Lot No(s).:
FF2587

Sincerely,

John A. Eltermann -S

Digitally signed by John A. Eltermann -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA,
ou=People, 0.9.2342.19200300.100.1.1=1300049305,
cn=John A. Eltermann -S
Date: 2021.08.23 09:39:41 -04'00'

For Peter Marks, MD, PhD
Director
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration

125742-0 /2229 /FC



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

August 23, 2021

Christopher Nagra
BioNTech Manufacturing GmbH
7000 Portage Road
Kalamazoo, Michigan 49001

Report on action taken on product submitted:

Released

COVID-19 Vaccine, mRNA

Lot No(s).:
FF2588

Sincerely,

John A. Eltermann -S

Digitally signed by John A. Eltermann -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People,
0.9.2342.19200300.100.1.1=1300049305, cn=John A. Eltermann -S
Date: 2021.08.23 09:38:42 -04'00'

Peter Marks, MD, PhD
Director
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration

125742-0 /2229 /FC



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

August 23, 2021

Christopher Nagra
BioNTech Manufacturing GmbH
7000 Portage Road
Kalamazoo, Michigan 49001

Report on action taken on product submitted:

Released

COVID-19 Vaccine, mRNA

Lot No(s).:
FF2590

Sincerely,

John A. Eltermann -S

Digitally signed by John A. Eltermann -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People,
0.9.2342.19200300.100.1.1=1300049305, cn=John A.
Eltermann -S
Date: 2021.08.23 09:37:00 -04'00'

For Peter Marks, MD, PhD
Director
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration

125742-0 /2229 /FC



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

August 23, 2021

Christopher Nagra
BioNTech Manufacturing GmbH
7000 Portage Road
Kalamazoo, Michigan 49001

Report on action taken on product submitted:

Released

COVID-19 Vaccine, mRNA

Lot No(s).:
FF2593

Sincerely,
John A. Eltermann -
S

For Peter Marks, MD, PhD
Director
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration

Digitally signed by John A. Eltermann -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA,
ou=People, 0.9.2342.19200300.100.1.1=1300049305,
cn=John A. Eltermann -S
Date: 2021.08.23 09:36:07 -04'00'

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

August 23, 2021

Christopher Nagra
BioNTech Manufacturing GmbH
7000 Portage Road
Kalamazoo, Michigan 49001

Report on action taken on product submitted:

Released

COVID-19 Vaccine, mRNA

Lot No(s).:
FF8841

Sincerely,

John A. Eltermann -S

Peter Marks, MD, PhD
Director
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration

Digitally signed by John A. Eltermann -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People,
0.9.2342.19200300.100.1.1=1300049305, cn=John A.
Eltermann -S
Date: 2021.08.23 09:35:05 -04'00'

125742-0 /2229 /FC



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

October 4, 2021

Christopher Nagra
BioNTech Manufacturing GmbH
7000 Portage Road
Kalamazoo, Michigan 49001

Report on action taken on product submitted:

Released

COVID-19 Vaccine, mRNA

Lot No(s).:
FH8027

Sincerely,

Joseph A. Quander -S

Digitally signed by Joseph A. Quander -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA,
ou=People, 0.9.2342.19200300.100.1.1=1300068705,
cn=Joseph A. Quander -S
Date: 2021.10.04 11:35:03 -04'00'

For

Peter Marks, MD, PhD
Director
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration

125742-0 /2229 /FC



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

October 4, 2021

Christopher Nagra
BioNTech Manufacturing GmbH
7000 Portage Road
Kalamazoo, Michigan 49001

Report on action taken on product submitted:

Released

COVID-19 Vaccine, mRNA

Lot No(s).:
FH8028

Sincerely,

Joseph A. Quander -S

Digitally signed by Joseph A. Quander -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA,
ou=People, 0.9.2342.19200300.100.1.1=1300068705,
cn=Joseph A. Quander -S
Date: 2021.10.04 11:33:35 -04'00'

For

Peter Marks, MD, PhD
Director
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration

125742-0 /2229 /FC