

QUERY 1

COMIRNATY is supplied in a multiple-dose vial that does not contain a preservative. Our review of the information provided in your BLA STN 125742/0 for COMIRNATY (COVID-19 mRNA Vaccine), for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older, is ongoing. Please note that 21 CFR 610.15(a) requires that “Products in multiple-dose containers shall contain a preservative,…” The regulations in 610.15(d) permit the approval of an exception or alternative to this requirement. Requests for such exceptions or alternatives must be in writing. Your submission does not include a request for an exception or alternative to the requirement of a preservative. Therefore, please submit a request and a justification for an exception or alternative to the requirement under 21 CFR 610.15(a) that products in multiple-dose vials include a preservative.

RESPONSE 1

The Sponsor acknowledges this request to submit a request and justification for an exception or alternative to the requirement under 21 CFR 610.15(a) that products in multiple-dose vials include a preservative. The formal request for an exception is provided in 1.12.5 Request for Exception to the 21 CFR 610.15(a) Requirement for a Preservative.

Literature References

None

SUPPORTING DOCUMENTATION

New or Replaced Supporting Documentation

[1.12.5 Request for Exception to the 21 CFR 610.15\(a\) Requirement for a Preservative](#), new

Previously submitted supporting documentation

None