COVID VACCINE - A BUNCH OF MALARKEY

FDA LICENSE LETTER TO PFIZER

An Intended Play on Words?

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'Never tell the truth to people who are not worthy of it.' -Mark Twain

The purpose of this report is to make the Public aware of a possible 'Coincidence' or 'Play on Words' about 1 of the Signatories of the FDA Letter to Pfizer regarding the Licensing of their new COVID-19 Injection. If one has had a chance to go through/read the Letter from the FDA to Pfizer about the Licensing of their newly approval of their COVID-19 Injection now named 'Comirnaty'? (Koe-mir'-na-tee) one has truly found it rather interesting or alarming as to what one of the Signatory's Name means.

But for the new name of the Injection, 'Comirnaty'… Interesting choice of Name? Apparently, it is a Compound Name. It is interesting how in one article reporting on the new Injection Name chosen by Pfizer called the Injection for what it is, a 'Product' and not a Vaccine. Here is an excerpt from an article following. Emphasis added.

'The name represents a combination of the terms COVID-19, mRNA, Community, and Immunity, to highlight the first authorization of a messenger RNA (mRNA) vaccine, as well as the Joint Global Efforts that made this achievement possible with unprecedented Rigor and Efficiency — and with Safety at the forefront — during this Global Pandemic, Pfizer and BioNTech said.'

Well, one knows how the Orwellian 'Ministry of Truth' of all World Governments like to 'Double Speak. They, like the Big Pharma Corporations incorporate, or 'splice and dice' all those many 'secret ingredients', Baby Parts. But they do not want the Public to know about or have to tell what is really on their 'Medical Products'. Might as well do that also for the Name of their Experimental Injection, now supposedly 'Fully Approved'. Or is it?

So, at the end of the FDA Licensing Letter, who are the Signatories? A Mary 'Malarkey'. Malarkey? Seriously? Are they playing the Plebs that bad? Yes. Correct one if needed, if one is wrong, but does that word, 'Malarkey' not mean in English, like 'Baloney' as in a Put-On or Falsity? Or is it just me?

Mary Malarkey
Director Office of Compliance
and Biologics Quality Research
Center for Biologics
Evaluation and Research

Merriam Webster's Definition of Malarkey
ma·lar·key | \ mə-ˈlär-kē | variants: or less commonly Malarky

: Insincere or Foolish Talk
: Bunkum He thinks that everything politicians say is a bunch of malarkey.

On a more serious note, the following is based on preliminary reports about the new Comirnaty Pfizer COVID-19 Injection. On Monday, August 23, 2021 the FDA is reported to have 'Approved' the new Medical Product of the new name, COMIRNATY. This product is not currently available in the United States. One should be reminded that the other COVID-19 Injections are not yet approved and still under Emergency Use Authorization.

The point is that any Government Mandates to take these Emergency ones that do not specify COMIRNATY are still illegal. It should be further noted that the FDA approved an 'Injectable Concoction' of Toxins that was designed to 'protect' People against COVID-19, but it is a virus that was released in 2020, if not earlier. The point is that such mRNA type of Injections are not 'programmed' for the Variants that are already chosen to be released, but first the 'Variants' are released to the Mass Media. You have the Delta, now the Lambda, etc.

Many have rightly noted that for the sake of the Pfizer Clinical Trials, Pfizer-BioNTech defined COVID-19 so that the most commonly experienced Adverse Events caused by their COVID-19 Injection, such as Fever, Chills and Muscle Pain, etc., could easily be confused with the Symptoms of mild COVID-19. The FDA in agreement with Pfizer conveniently did not include other Symptoms such as Fatigue, Headache and Joint Pain in their definition of COVID-19. Dr. Rochelle Walineski, the Director of the CDC in the USA, had this to say about those who have been 'Vaccinated' with their COVID-19 Injections.

'Additionally, reports from our International Colleagues including Israel suggest Increased Risk of Severe Disease amongst those Vaccinated early. Given this Body of Evidence, we are concerned that the current Strong Protection against Severe Infection, Hospitalization and Death could decrease in the months ahead, especially among those who are at Higher Risk or who were vaccinated. Earlier during the Phases of our Vaccination Rollout suggest Increased Risk of Severe Disease amongst those Vaccinated early.'

Here is an excerpt from a great Article published by the Children's Health Defense. This is the Legal Agency headed-up by Robert Kennedy Jr. The tile of the Article is as follows. '2 Things Mainstream Media Didn't Tell You About FDA's Approval of Pfizer Vaccine.' The link will be in the Endnotes. 'Americans, told that the Pfizer COVID vaccine is now licensed, will understandably assume COVID vaccine mandates are lawful. But only EUA-authorized vaccines, for which no one has any real liability, will be available during the next few weeks when many school mandate deadlines occur.' The FDA appears to be purposefully tricking American citizens into giving up their right to refuse an experimental product.

Devil in the Details
While the media has trumpeted that the FDA has approved COVID vaccines, the FDA has not approved the Pfizer BioNTech so-called 'vaccines'. Nor has the FDA approved any COVID-19 Injections for the 12- to 15-year age group. This 'Authorization' does not also include any Subsequent Booster doses. So, to reiterate, the FDA has not Licensed nor 'Fully Approved' any Emergency Use Authorization COVID-19 Injection.

They have only Licensed the Pfizer Medical Product of a COVID-19 Injection now to be called "Comirnaty'. And this only from August 23, 2021 going forward. Those other COVID-19 Big Pharma Companies like Moderna and there 'Computer Downloadable' vaccine, nor any vaccine from Johnson & Johnson are not Fully Approved. The Point? They cannot be forced upon People to enter Hospitals, Restaurants, Grocery Stores, be on Public Transport, or attend Schools, etc.

To do this is violated the Nuremberg Code, the U.N. Code and in the USA, the Civil Liberties of every Constitutional Citizen. What do People do? What can they do? Here is what People need to know when somebody orders them to get the COVID-19 Injections in order to keep one's Job or Livelihood. Ask to see the vial. If it says 'Comirnaty', it is the FDA Licensed Medical Product. Now this is then another issue altogether. Even if the FDA has 'legally' Authorized a Licensing for a Big Pharma Company to sell their Medical Products, it does not mean People should still be getting it.

Just because the Hospitals will be switching labels does not mean that the solution within the COVID-19 vial has 'magically' become 'Safe and Effective'. It has not. If a vial says 'Pfizer-BioNTech,' then it is still from the Experimental Batch and a Medical Product under the Section 21 U.S. Code 360bbb. Meaning? A person has the Legal Right to refuse based on Informed Consent that no Experimental Medical Device and/or Procedure can be made forcefully upon a person. Even in the very Fact Sheets of the Emergency Use Authorization condition, it is plainly stated that a person has the right to refuse such an Experimental Medical Procedure. The FDA in collaboration with the money-contributing Big Pharma's are playing, 'Bait and Switch' with the World.

The People of the world must recognize and understand that Government Mandates are not Law. The current COVID-19 Medical Tyranny that has come down and been allowed to stand from un-constitutional Bureaucratic Agencies and Bureaucrats are not authorized to make Laws and be the Legislators of such. The COVID-19 Injections are still under EUA only, and under 'Further Extension, as Pfizer's Clinical Trails are set for 2027/8. Although the Mass Media is broadcasting otherwise, People have a choice.

To reiterate, the FDA just approved the 'Old' Pfizer 'Vaccine' which is now the New one rebranded as 'Comirnaty'. The BioNtec Covid-19 is still under EUA and both are under EUA for ages 12-15 and both are under EUA for 3rd Doses. The following is that FDA Licensing Letter to Pfizer in its entirety. Notice, again the Signatory, Mary A. 'Malarkey'. Is this COVID-19 plandemic and letter 'Authorizing' a 'Poison Death Shot' as Dr. Zelenko has called nothing more than 'Malarkey'? Yes.

Our STN: BL 125742/0 BLA APPROVAL

BioNTech Manufacturing GmbH
Attention: Amit Patel
Pfizer Inc.
235 East 42nd Street
New York, NY 10017

August 23, 2021

Dear Mr. Patel:

Please refer to your Biologics License Application (BLA) submitted and received on May 18, 2021, under section 351(a) of the Public Health Service Act (PHS Act) for COVID-19 Vaccine, mRNA.

LICENSING

We are issuing Department of Health and Human Services U.S. License No. 2229 to BioNTech Manufacturing GmbH, Mainz, Germany, under the provisions of section 351(a) of the PHS Act controlling the manufacture and sale of biological products. The license authorizes you to introduce or deliver for introduction into interstate commerce, those products for which your company has demonstrated compliance with establishment and product standards.

Under this license, you are authorized to manufacture the product, COVID-19 Vaccine, mRNA, which is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

The review of this product was associated with the following National Clinical Trial (NCT) numbers: NCT04368728 and NCT04380701.

MANUFACTURING LOCATIONS

Under this license, you are approved to manufacture COVID-19 Vaccine, mRNA drug substance at (b) (4)

The final formulated product will be manufactured, filled, labeled and packaged at Pfizer (b) (4)

. The diluent, 0.9% Sodium Chloride Injection, USP, will be manufactured at (b) (4)

You may label your product with the proprietary name, COMIRNATY, and market it in 2.0 mL glass vials, in packages of 25 and 195 vials.
We did not refer your application to the Vaccines and Related Biological Products Advisory Committee because our review of information submitted in your BLA, including the clinical study design and trial results, did not raise concerns or controversial issues that would have benefited from an advisory committee discussion.

DATING PERIOD

The dating period for COVID-19 Vaccine, mRNA shall be 9 months from the date of manufacture when stored between -90ºC to -60ºC (-130ºF to -76ºF). The date of manufacture shall be no later than the date of final sterile filtration of the formulated drug product (at (b) (4) , the date of manufacture is defined as the date of sterile filtration for the final drug product; at
Pfizer (b) (4) , it is defined as the date of the (b) (4)
Following the final sterile filtration, (b) (4)
, no
reprocessing/reworking is allowed without prior approval from the Agency. The dating period for your drug substance shall be (b) (4) when stored at (b) (4) We have approved the stability protocols in your license application for the purpose of extending the expiration dating period of your drug substance and drug product under 21 CFR 601.12.

FDA LOT RELEASE

Please submit final container samples of the product in final containers together with protocols showing results of all applicable tests. You may not distribute any lots of product until you receive a notification of release from the Director, Center for Biologics Evaluation and Research (CBER).

BIOLOGICAL PRODUCT DEVIATIONS

You must submit reports of biological product deviations under 21 CFR 600.14. You should identify and investigate all manufacturing deviations promptly, including those associated with processing, testing, packaging, labeling, storage, holding and distribution. If the deviation involves a distributed product, may affect the safety, purity, or potency of the product, and meets the other criteria in the regulation, you must submit a report on Form FDA 3486 to the Director, Office of Compliance and Biologics Quality, electronically through the eBPDR web application or at the address below. Links for the instructions on completing the electronic form (eBPDR) may be found on CBER's web site at https://www.fda.gov/vaccines-blood-biologics/report-problem-center-biologics-evaluation-research/biological-product-deviations:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center

10903 New Hampshire Ave.
WO71-G112
Silver Spring, MD 20993-0002

MANUFACTURING CHANGES

You must submit information to your BLA for our review and written approval under 21 CFR 601.12 for any changes in, including but not limited to, the manufacturing, testing, packaging or labeling of COVID-19 Vaccine, mRNA, or in the manufacturing facilities.

LABELING

We hereby approve the draft content of labeling including Package Insert, submitted under amendment 74, dated August 21, 2021, and the draft carton and container labels submitted under amendment 63, dated August 19, 2021.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the final content of labeling (21 CFR 601.14) in Structured Product Labeling (SPL) format via the FDA automated drug registration and listing system, (eLIST) as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the Package Insert submitted on August 21, 2021. Information on submitting SPL files using eLIST may be found in the guidance for industry SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND CONTAINER LABELS

Please electronically submit final printed carton and container labels identical to the carton and container labels submitted on August 19, 2021, according to the guidance for industry Providing Regulatory Submissions in Electronic Format — Certain Human

Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-certain-human-pharmaceutical-product-applications.

All final labeling should be submitted as Product Correspondence to this BLA STN BL 125742 at the time of use and include implementation information on Form FDA 356h.

ADVERTISING AND PROMOTIONAL LABELING

You may submit two draft copies of the proposed introductory advertising and promotional labeling with Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research Document Control Center 10903 New Hampshire Ave.
WO71-G112
Silver Spring, MD 20993-0002

You must submit copies of your final advertising and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 (21 CFR 601.12(f)(4)).

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

ADVERSE EVENT REPORTING

You must submit adverse experience reports in accordance with the adverse experience reporting requirements for licensed biological products (21 CFR 600.80), and you must submit distribution reports at monthly intervals as described in 21 CFR 600.81. For information on adverse experience reporting, please refer to the guidance for industry Providing Submissions in Electronic Format —Postmarketing Safety Reports for Vaccines at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-submissions-electronic-format-postmarketing-safety-reports-vaccines. For information on distribution reporting, please refer to the guidance for industry Electronic Submission of Lot Distribution Reports at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Post-MarketActivities/LotReleases/ucm061966.htm.

PEDIATRIC REQUIREMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are deferring submission of your pediatric studies for ages younger than 16 years for this application because this product is ready for approval for use in individuals 16 years of age and older, and the pediatric studies for younger ages have not been completed.

Your deferred pediatric studies required under section 505B(a) of the Federal Food, Drug, and Cosmetic Act (FDCA) are required postmarketing studies. The status of these postmarketing studies must be reported according to 21 CFR 601.28 and section 505B(a)(4)(C) of the FDCA. In addition, section 506B of the FDCA and 21 CFR 601.70 require you to report annually on the status of any postmarketing commitments or required studies or clinical trials.

Label your annual report as an "Annual Status Report of Postmarketing Study Requirement/Commitments" and submit it to the FDA each year within 60 calendar days of the anniversary date of this letter until all Requirements and Commitments subject to the reporting requirements under section 506B of the FDCA are released or fulfilled. These required studies are listed below:

1. Deferred pediatric Study C4591001 to evaluate the safety and effectiveness of COMIRNATY in children 12 years through 15 years of age.

Final Protocol Submission: October 7, 2020

Study Completion: May 31, 2023

Final Report Submission: October 31, 2023

2. Deferred pediatric Study C4591007 to evaluate the safety and effectiveness of COMIRNATY in infants and children 6 months to <12 years of age.

Final Protocol Submission: February 8, 2021

Study Completion: November 30, 2023

Final Report Submission: May 31, 2024

3. Deferred pediatric Study C4591023 to evaluate the safety and effectiveness of COMIRNATY in infants <6 months of age.

Final Protocol Submission: January 31, 2022
Study Completion: July 31, 2024
Final Report Submission: October 31, 2024

Submit the protocols to your IND 19736, with a cross-reference letter to this BLA STN BL 125742 explaining that these protocols were submitted to the IND. Please refer to the PMR sequential number for each study/clinical trial and the submission number as shown in this letter.
Submit final study reports to this BLA STN BL 125742. In order for your PREA PMRs to be considered fulfilled, you must submit and receive approval of an efficacy or a labeling

supplement. For administrative purposes, all submissions related to these required pediatric postmarketing studies must be clearly designated as:

- **Required Pediatric Assessment(s)**

We note that you have fulfilled the pediatric study requirement for ages 16 through 17 years for this application.

POSTMARKETING REQUIREMENTS UNDER SECTION 505(o)

Section 505(o) of the Federal Food, Drug, and Cosmetic Act (FDCA) authorizes FDA to require holders of approved drug and biological product applications to conduct postmarketing studies and clinical trials for certain purposes, if FDA makes certain findings required by the statute (section 505(o)(3)(A), 21 U.S.C. 355(o)(3)(A)).

We have determined that an analysis of spontaneous postmarketing adverse events reported under section 505(k)(1) of the FDCA will not be sufficient to assess known serious risks of myocarditis and pericarditis and identify an unexpected serious risk of subclinical myocarditis.

Furthermore, the pharmacovigilance system that FDA is required to maintain under section 505(k)(3) of the FDCA is not sufficient to assess these serious risks.

Therefore, based on appropriate scientific data, we have determined that you are required to conduct the following studies:

4. Study C4591009, entitled “A Non-Interventional Post-Approval Safety Study of the Pfizer-BioNTech COVID-19 mRNA Vaccine in the United States,” to evaluate the occurrence of myocarditis and pericarditis following administration of COMIRNATY.

We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

Final Protocol Submission: August 31, 2021
Monitoring Report Submission: October 31, 2022
Interim Report Submission: October 31, 2023
Study Completion: June 30, 2025
Final Report Submission: October 31, 2025

5. Study C4591021, entitled “Post Conditional Approval Active Surveillance Study Among Individuals in Europe Receiving the Pfizer-BioNTech Coronavirus

Disease 2019 (COVID-19) Vaccine," to evaluate the occurrence of myocarditis and pericarditis following administration of COMIRNATY.

We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

Final Protocol Submission: August 11, 2021

Progress Report Submission: September 30, 2021

Interim Report 1 Submission: March 31, 2022

Interim Report 2 Submission: September 30, 2022

Interim Report 3 Submission: March 31, 2023

Interim Report 4 Submission: September 30, 2023

Interim Report 5 Submission: March 31, 2024

Study Completion: March 31, 2024

Final Report Submission: September 30, 2024

6. Study C4591021 substudy to describe the natural history of myocarditis and pericarditis following administration of COMIRNATY.

We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

Final Protocol Submission: January 31, 2022
Study Completion: March 31, 2024
Final Report Submission: September 30, 2024

7. Study C4591036, a prospective cohort study with at least 5 years of follow-up for potential long-term sequelae of myocarditis after vaccination (in collaboration with Pediatric Heart Network).

We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

Final Protocol Submission: November 30, 2021
Study Completion: December 31, 2026

Final Report Submission: May 31, 2027

8. Study C4591007 substudy to prospectively assess the incidence of subclinical myocarditis following administration of the second dose of COMIRNATY in a subset of participants 5 through 15 years of age.

We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this assessment according to the following schedule: Final Protocol Submission: September 30, 2021

Study Completion: November 30, 2023
Final Report Submission: May 31, 2024

9. Study C4591031 substudy to prospectively assess the incidence of subclinical myocarditis following administration of a third dose of COMIRNATY in a subset of participants 16 to 30 years of age.

We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

Final Protocol Submission: November 30, 2021
Study Completion: June 30, 2022
Final Report Submission: December 31, 2022

Please submit the protocols to your IND 19736, with a cross-reference letter to this BLA STN BL 125742 explaining that these protocols were submitted to the IND. Please refer to the PMR sequential number for each study/clinical trial and the submission number as shown in this letter.

Please submit final study reports to the BLA. If the information in the final study report supports a change in the label, the final study report must be submitted as a supplement to this BLA STN BL 125742. For administrative purposes, all submissions related to these postmarketing studies required under section 505(o) must be submitted to this BLA and be clearly designated as:

- **Required Postmarketing Correspondence under Section 505(o)**
- **Required Postmarketing Final Report under Section 505(o)**
- **Supplement contains Required Postmarketing Final Report under Section 505(o)**

Section 505(o)(3)(E)(ii) of the FDCA requires you to report periodically on the status of any study or clinical trial required under this section. This section also requires you to periodically report to FDA on the status of any study or clinical trial otherwise

undertaken to investigate a safety issue. In addition, section 506B of the FDCA and 21 CFR 601.70 require you to report annually on the status of any postmarketing commitments or required studies or clinical trials.

You must describe the status in an annual report on postmarketing studies for this product. Label your annual report as an Annual Status Report of Postmarketing Requirements/Commitments and submit it to the FDA each year within 60 calendar days of the anniversary date of this letter until all Requirements and Commitments subject to the reporting requirements of section 506B of the FDCA are fulfilled or released. The status report for each study should include:

- the sequential number for each study as shown in this letter;
- information to identify and describe the postmarketing requirement;
- the original milestone schedule for the requirement;
- the revised milestone schedule for the requirement, if appropriate;
- the current status of the requirement (i.e., pending, ongoing, delayed, terminated, or submitted); and,
- an explanation of the status for the study or clinical trial. The explanation should include how the study is progressing in reference to the original projected schedule, including, the patient accrual rate (i.e., number enrolled to date and the total planned enrollment).

As described in 21 CFR 601.70(e), we may publicly disclose information regarding these postmarketing studies on our website at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/default.htm.

We will consider the submission of your annual report under section 506B of the FDCA and 21 CFR 601.70 to satisfy the periodic reporting requirement under section 505(o)(3)(E)(ii) provided that you include the elements listed in section 505(o) and 21 CFR 601.70. We remind you that to comply with section 505(o), your annual report must also include a report on the status of any study or clinical trial otherwise undertaken to investigate a safety issue. Failure to periodically report on the status of studies or clinical trials required under section 505(o) may be a violation of FDCA section 505(o)(3)(E)(ii) and could result in regulatory action.

POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

We acknowledge your written commitments as described in your letter of August 21, 2021 as outlined below:

10. Study C4591022, entitled “Pfizer-BioNTech COVID-19 Vaccine Exposure during Pregnancy: A Non-Interventional Post-Approval Safety Study of Pregnancy and Infant Outcomes in the Organization of Teratology Information Specialists (OTIS)/MotherToBaby Pregnancy Registry.”

Final Protocol Submission: July 1, 2021

Study Completion: June 30, 2025

Final Report Submission: December 31, 2025

11. Study C4591007 substudy to evaluate the immunogenicity and safety of lower dose levels of COMIRNATY in individuals 12 through <30 years of age.

Final Protocol Submission: September 30, 2021

Study Completion: November 30, 2023

Final Report Submission: May 31, 2024

12. Study C4591012, entitled “Post-emergency Use Authorization Active Safety Surveillance Study Among Individuals in the Veteran’s Affairs Health System Receiving Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine.”
Final Protocol Submission: January 29, 2021

Study Completion: June 30, 2023

Final Report Submission: December 31, 2023

13. Study C4591014, entitled “Pfizer-BioNTech COVID-19 BNT162b2 Vaccine Effectiveness Study - Kaiser Permanente Southern California.”

Final Protocol Submission: March 22, 2021
Study Completion: December 31, 2022
Final Report Submission: June 30, 2023

Please submit clinical protocols to your IND 19736, and a cross-reference letter to this BLA STN BL 125742 explaining that these protocols were submitted to the IND. Please refer to the PMC sequential number for each study/clinical trial and the submission number as shown in this letter.

If the information in the final study report supports a change in the label, the final study report must be submitted as a supplement. Please use the following designators to prominently label all submissions, including supplements, relating to these postmarketing study commitments as appropriate:

- Postmarketing Commitment – Correspondence Study Update
- Postmarketing Commitment – Final Study Report
- Supplement contains Postmarketing Commitment – Final Study Report

For each postmarketing study subject to the reporting requirements of 21 CFR 601.70, you must describe the status in an annual report on postmarketing studies for this product. Label your annual report as an Annual Status Report of Postmarketing Requirements/Commitments and submit it to the FDA each year within 60 calendar days of the anniversary date of this letter until all Requirements and Commitments subject to the reporting requirements of section 506B of the FDCA are fulfilled or released. The status report for each study should include:

- the sequential number for each study as shown in this letter;
- information to identify and describe the postmarketing commitment;
- the original schedule for the commitment;
- the status of the commitment (i.e., pending, ongoing, delayed, terminated, or submitted); and,
- an explanation of the status including, for clinical studies, the patient accrual rate (i.e., number enrolled to date and the total planned enrollment).

As described in 21 CFR 601.70(e), we may publicly disclose information regarding these postmarketing studies on our website at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/default.htm.

POST APPROVAL FEEDBACK MEETING

New biological products qualify for a post approval feedback meeting. Such meetings are used to discuss the quality of the application and to evaluate the communication process during drug development and marketing application review. The purpose is to learn from successful aspects of the review process and to identify areas that could benefit from improvement. If you would like to have such a meeting with us, please contact the Regulatory Project Manager for this application.

Sincerely,

Mary A. Malarkey
Director
Office of Compliance and
Biologics Quality Center
for Biologics Evaluation
and Research

Marion F. Gruber, PhD
Director
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research

Buyer Beware
Since the Letter by the FDA licensing the Pfizer Corporation to sell and distribute their COVID-19 Injection under a New Label, many Skeptics and Critics of the whole COVID-19 plandemic believe is not a valid 'Authorization' and in fact misleading the Public and World at large. It has been reported that the FDA actually issued out 2 Letters on August 23, 2021. One Letter actually extended the EUA for the Pfizer vaccine while granting approval to a different vaccine called 'Comirnaty' which does not exist yet in the Market and not in production either.

The Second Letter attested to the fact that the current supply of millions of Pfizer Experimental Vails not 'authorized' will/can be used in lieu of the shortage of the supply. How convenient. So, it is a classic 'Bait and Switch' operation fooling the World into thinking the present Pfizer COVID-19 'Vaccine' now has full approval, all while making sure Pfizer still has legal immunity under the EUA for all the injuries and deaths caused by its vaccine, not the Comirnaty one.

And, just as worse is the bought and paid for Mass Media that has played along mis-reporting that the Pfizer COVID-19 Vaccine has now been, 'Fully Approved'. What the Skeptics and Critics of the Government and Big Pharma Company say is that the reason why there is a hesitancy on the part of the Big Pharma Companies to start the mass production of their new Comirnaty Product as in the case of Pfizer is that they need to push the 'Product' that is on the shelves first. It is treated like a 'Commodity' and People are expendable.

Further, that once the Comirnaty Medical Product rolls-out into the Market and is being injected into the veins of People, any Adverse Event, the Company can now be directly liable for damages. However, one is confident the army of Government and Big Pharma Corporate Lawyers will make sure somehow the damages get passed on to be covered by the U.S. Taxpayer.

But to reiterate, the Pfizer 'Vaccine' is not a vaccine. Even the CDC's own Director Walensky admits the COVID-19 'Vaccines' do not halt Transmission and do not prevent Infections. It merely reduces Symptoms and with lessoning Immunity, thus the need for lifelong 'Boosters'. In actuality, Scientific Studies are starting to show that indeed, it is the 'Vaccinated' that allows such People to become Super Spreaders of the Spike Proteins as the 'Variants' because they appear to be asymptomatic while they actually carry a far higher viral load.

This is the hypothesis being put for by Doctors like Dr. Peter McCullough of Texas in the USA. What the COVID-19 Injections are increasingly accomplishing however, is Mass Death of the 'Vaccinated. This is presently being done through Micro Blood Clots of the Heart and/or Brain. It is compromising the Health of those with Auto-Immune Disorders, etc. A website called The Covid Blog is documenting many of the shocking, disturbing Deaths. There is also the VEARS reporting website of the CDC. See links below.

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Main Sources

FDA Letter to Pfizer for Biologics License Application (BLA)
https://www.fda.gov/media/151710/download

Other Resources

2 Things Mainstream Media Didn't Tell You About FDA's Approval of Pfizer Vaccine.
https://childrenshealthdefense.org/defender/mainstream-media-fda-approval-pfizer-vaccine/

Study: Fully Vaccinated Healthcare Workers Carry 251 Times Viral Load, Pose Threat to Unvaccinated Patients, Co-Workers.
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