

Wait, Uncle Joe, What FDA Approval – Webpage Copy 8.24.21

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Now at

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Copied here in full anyway –

Wait, Uncle Joe, What FDA Approval?

August 24, 2021 by IWB

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By Chris Black

Let me say this loud and clear: If you are one of the millions of Americans who have said that you will get the shot when it had full FDA approval — that has now happened.

The moment you have been waiting for is here — and the time to get vaccinated is today.

— President Biden (@POTUS) [August 23, 2021](#)

President Biden calls on more companies to require COVID vaccine for workers now that the Pfizer shot has full FDA approval: "Vaccination requirements have been around for decades...It only makes sense to require a vaccine to stop the spread of COVID-19" t.co/kj6CrKHAoT
pic.twitter.com/0yjn8fiXKc

— CBS News (@CBSNews) August 23, 2021

I read the actual documents. I couldn't find one with a signature from the FDA that announced full approval of administration, only the manufacture under the new brand name.

There is no FDA approval at all, just an extension of the EUA with some clarifications.

Lies on top of lies.

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Wording directly from the [FDA](#):

On August 23, 2021, having concluded that revising this EUA is appropriate to protect the public health or safety under section 564(g)(2) of the Act, FDA is reissuing the August 12, 2021 letter of authorization in its entirety with revisions incorporated to clarify that the EUA will remain in place for the Pfizer-BioNTech COVID-19 vaccine for the previously-authorized indication and uses, and to authorize use of COMIRNATY (COVID-19 Vaccine, mRNA) under this EUA for certain uses that are not included in the approved BLA. In addition, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) was revised to provide updates on expiration dating of the authorized Pfizer-BioNTech COVID-19 Vaccine and to update language regarding warnings and precautions related to myocarditis and pericarditis. The Fact Sheet for Recipients and Caregivers was updated as the Vaccine Information Fact Sheet for Recipients and Caregivers, which comprises the Fact Sheet for the authorized Pfizer-BioNTech COVID-19 Vaccine and information about the FDA-licensed vaccine, COMIRNATY

NOWHERE IN THE DOCUMENT DOES IT MENTION FULL APPROVAL OF THE VACCINE OUTSIDE THE EMERGENCY USE AUTHORIZATION.

19. *Criteria for Issuance of Authorization*

I have concluded that the emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 when administered as described in the Scope of Authorization (Section II) meets the criteria for issuance of an authorization under Section 564(c) of the Act, because:

A. SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

B. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective in preventing COVID-19, and that, when used under the conditions described in this authorization, the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine when used to prevent COVID-19 outweigh its known and potential risks; and

C. There is no adequate, approved, and available alternative to the emergency use of Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19.

There is a lot of *may* in that thing. Funny how they can't approve the shot if there is a viable alternative.

Now you know why ivermectin is a bad word.

This is from the last page of the authorization. I don't know how you get clearer.

See also [OFFICIAL FDA APPROVAL PRESS RELEASE : "we have no clue of long term side effects"](#)

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Conditions Related to Printed Matter, Advertising, and Promotion

X. All descriptive printed matter, advertising, and promotional material, relating to the use of the Pfizer-BioNTech COVID-19 Vaccine shall be consistent with the authorized labeling, as well as the terms set forth in this EUA, and meet the requirements set forth in section 502(a) and (n) of the FD&C Act and FDA implementing regulations.

Y. All descriptive printed matter, advertising, and promotional material relating to the use of the Pfizer-BioNTech COVID-19 Vaccine clearly and conspicuously shall state clearly

This product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus

Disease 2019 (COVID-19) for use in individuals 12 years of age and older; and

• The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

More stuff from the approval. It turns out it is an approval to manufacture, not administer.

The administration of the jab is still only under the EUA.

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.

They also have to report all adverse events to the FDA.

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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 www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-submissions-electronic-format-postmarketing-safety-reports-vaccines*

Hmm, the trials aren't done?

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

Wait what, there isn't enough data to determine the risks? It isn't going to be done until 2025???

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

See also [President Biden's daily job approval % will be down again today - to a new historic low.](#)

I rest my case.

Remember, nobody ever died before Covid. Anyone that dies, even if they are 92 with dementia, stage four cancer, and sepsis, would have survived had it not been for Covid. Covid is the only thing that can actually kill a person today.

Walking outside without a mask for even ten seconds is enough to ravage your body with Delta. You will not survive unless you are vaccinated. If you are vaccinated you will still get Covid and be able to spread it, but you will survive. However if an unvaccinated person comes into contact with you, they will give you a mutant version that will evade your vaccine.

You will die. That is why everyone must be forced into getting the vaccine. There is no natural immunity to Covid.

There are no treatments for Covid. Anything you have heard about drugs like Ivermectin and Hydroxychloroquine is lies spewed by white supremacists trying to undermine the authority of global governments.

Doctors attempting to treat patients with these drugs are committing crimes against humanity. All talk of these treatments shall be purged from all outlets. Only the consensus of government experts is correct and shall be disseminated.

The tests are 100% accurate and never make mistakes. That is why everyone must be tested multiple times a week. You may be infected and never even know, until you stop breathing and die.

During that time, you may have infected millions of people and are responsible for killing thousands of grandparents. How would you like to be the one who kills a little girl's grandmother?

So stay in your home. Never go out unless it is an emergency. If you do, wear a mask, keep your distance and do not talk to anyone. The act of talking, even with a mask can cause virus to travel hundreds of miles and infect people just minding their own business and following the health guidelines.

Children cannot be trusted to follow our guidance, so they must be removed from parents and vaccinated. They will also be kept in facilities until the crisis is over. It is the only way to keep them safe.

This is not ramblings of crazy nut jobs. This is actually a story based on things the media and "experts" have said.

This is our new reality.

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approval, uncle