Medical Countermeasures Awareness Bill

Template legislation for introduction, deliberation and adoption by any governmental entity that levies and distributes taxes: city/town, school district, county, state and federal.

Medical Countermeasures Awareness Bill

Every entity (public, private and/or public-private) receiving federal [state, county, local, school district] funds who makes any announcements, statements and/or declarations regarding any medical countermeasure, for example, statements about the medical countermeasure's availability, purpose, safety, efficacy, history of development, etc., shall simultaneously include the following notice to prospective users and recipients:

> Pursuant to Section 564 of the Food Drug and Cosmetics Act, 21 USC 360bbb, governing use of "Emergency Use Authorization" (EUA) products, as amended by the Pandemic and All-Hazards Preparedness Act (PAHPRA) of 2013 and related federal legislation, and the Supremacy Clause of the United States Constitution (Article VI, Clause 2),
>
> [NAME OF MEDICAL COUNTERMEASURE] manufactured by [NAME OF MANUFACTURER] has been exempted from testing using Good Laboratory Practices; from Good Clinical Practice, including informed consent; from Good Manufacturing Practice; and from being assessed to determine if Risk Evaluation and Mitigation Strategies (REMS) are necessary.
>
> Safety regulations governing the manufacture, shipment, holding, dispensing, administration and labeling of [NAME OF MEDICAL COUNTERMEASURE] manufactured by [NAME OF MANUFACTURER] do not apply to this product.
>
> No Federal or State agency assures that the contents of the batch of [NAME OF MEDICAL COUNTERMEASURE] manufactured by [NAME OF MANUFACTURER], from which the dose you are about to receive was taken, has similar contents to any other batch of [NAME OF MEDICAL COUNTERMEASURE] manufactured by [NAME OF MANUFACTURER], making any practical determination of the safety of your dose of [NAME OF MANUFACTURER] manufactured by [NAME OF MANUFACTURER] impossible.

Failure for any entity to comply will result in loss of all federal (state) funding until compliance occurs.

References:

January 2017 Emergency Use Authorization of Medical Products and Related Authorities, Guidance for Industry and Other Stakeholders, Procedural OMB Control No. 0910-0595 Expiration Date 09/30/2025[1], particularly pages 15, 22-25, 27, 28, 33, and 39-41.

April 2019 Risk Evaluation and Mitigation Strategies (REMS): FDA's Application of Statutory Factors in Determining When a REMS Is Necessary, Guidance for Industry, April 2019 [2]

PowerPoint briefings on Section 564 of the FD&C Act [3]

- August 25-27, 2020 - FDA-CDC Joint Learning Session, Regulatory Updates on Use of Medical Countermeasures Preparedness Summit.[4] (FDA-Office of Counterterrorism and Emerging Threats Regulatory Counsel Elizabeth Sadove.)
- Feb. 10, 2021 PHEP Connects Webinar; Emergency Response Authorities and Access to Medical Countermeasures (FDA-OCET Regulatory Counsel, Brooke Courtney)
- March 1, 2021 - American Bar Association Health Law Section Overview of FDA's Emergency Use Authorization (EUA) Authority & COVID-19 Response (FDA-OCET Regulatory Counsel Brooke Courtney)
- March 18, 2021 - Council of State and Territorial Epidemiologists, Public Health Law Webinar; Overview of FDA's Emergency Use Authorization (EUA) Authority: Implications for COVID-19 Vaccination [5] (FDA-OCET Regulatory Counsel Brooke Courtney)
- April 2021 - 2021 Preparedness Summit, Tri-Agency Task Force for Emergency Diagnostics Session, Overview from FDA[6] (FDA-OCET Regulatory Counsel Jennifer Ross)
- May 15, 2021 - Pennsylvania Society for Post-Acute and Long-Term Care Medicine, Spring Symposium, FDA's EUAs and Other Related Authorities [7] (FDA-OCET Regulatory Counsel Jennifer Ross)
- Nov. 21, 2021 - BARDA (Biomedical Advanced Research and Development Authority) Industry Day. FDA's EUAs and Other Related Authorities [8] (FDA-OCET)

[1] www.fda.gov/media/97321/download
[2] https://www.fda.gov/media/100307/download
[3] https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/mcm-related-legal-and-policy-presentations-publications-and-qas
[4] https://public4.pagefreezer.com/browse/FDA/15-09-2022T08:43/https://www.fda.gov//media/154536/download
[5] https://www.fda.gov/media/154527/download?attachment
[6] https://www.fda.gov/media/154310/download?attachment
[7] https://www.fda.gov/media/154313/download?attachment
[8] https://www.fda.gov/media/154532/download?attachment