

21 U.S. Code § 360bbb-4b

Medical countermeasure master files

(a) Applicability of reference

(1) In general

A person may submit data and information in a master file to the Secretary with the intent to reference, or to authorize, in writing, another person to reference, such data or information to support a medical countermeasure submission (including a supplement or amendment to any such submission), without requiring the master file holder to disclose the data and information to any such persons authorized to reference the master file. Such data and information shall be available for reference by the master file holder or by a person authorized by the master file holder, in accordance with applicable privacy and confidentiality protocols and regulations.

(2) Reference of certain master files

In the case that data or information within a medical countermeasure master file is used only to support the conditional approval of an application filed under section 360ccc of this title, such master file may be relied upon to support the effectiveness of a product that is the subject of a subsequent medical countermeasure submission only if such application is supplemented by additional data or information to support review and approval in a manner consistent with the standards applicable to such review and approval for such countermeasure, qualified countermeasure, or qualified pandemic or epidemic product.

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