

countermeasure, qualified countermeasure, or qualified pandemic or epidemic product. The Secretary may rely upon the data and information within the medical countermeasure master file for which such written notification was provided in additional applications, as applicable and appropriate and upon the request of the master file holder so notified in writing or by an authorized person of such holder.

“(2) CERTAIN APPLICATIONS.—If the Secretary has reviewed and relied upon specified data or information within a medical countermeasure master file to support the conditional approval of an application under section 571 to subsequently support the approval, clearance, licensure, or authorization of a security countermeasure, qualified countermeasure, or qualified pandemic or epidemic product, the Secretary shall provide a brief written description to the master file holder regarding the elements of the application fulfilled by the data or information within the master file and how such data or information contained in such application meets the standards of evidence under subsection (c) or (d) of section 505, subsection (d) of section 512, or section 351 of the Public Health Service Act (as applicable), which shall not include any trade secret or confidential commercial information.

“(e) RULES OF CONSTRUCTION.—Nothing in this section shall be construed to—

“(1) limit the authority of the Secretary to approve, license, clear, conditionally approve, or authorize drugs, biological products, or devices pursuant to, as applicable, this Act or section 351 of the Public Health Service Act (as such applicable Act is in effect on the day before the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019), including the standards of evidence, and applicable conditions, for approval under the applicable Act;

“(2) alter the standards of evidence with respect to approval, licensure, or clearance, as applicable, of drugs, biological products, or devices under this Act or section 351 of the Public Health Service Act, including, as applicable, the substantial evidence standards under sections 505(d) and 512(d) or this Act and section 351(a) of the Public Health Service Act; or

“(3) alter the authority of the Secretary under this Act or the Public Health Service Act to determine the types of data or information previously submitted by a sponsor or any other person that may be incorporated by reference in an application, request, or notification for a drug, biological product, or device submitted under sections 505(i), 505(b), 505(j), 512(b)(1), 512(b)(2), 512(j), 564, 571, 520(g), 515(c), 513(f)(2), or 510(k) of this Act, or subsection (a) or (k) of section 351 of the Public Health Service Act, including a supplement or amendment to any such submission, and the requirements associated with such reference.

“(f) DEFINITIONS.—In this section:

“(1) The term ‘master file holder’ means a person who submits data and information to the Secretary with the intent to reference or authorize another person to reference such data or information to support a medical countermeasure submission, as described in subsection (a).