INFORMATION SECURITY

FDA Needs to Rectify Control Weaknesses That Place Industry and Public Health Data at Risk

What GAO Found

Although the Food and Drug Administration (FDA), an agency of the Department of Health and Human Services (HHS), has taken steps to safeguard the seven systems GAO reviewed, a significant number of security control weaknesses jeopardize the confidentiality, integrity, and availability of its information and systems. The agency did not fully or consistently implement access controls, which are intended to prevent, limit, and detect unauthorized access to computing resources. Specifically, FDA did not always (1) adequately protect the boundaries of its network, (2) consistently identify and authenticate system users, (3) limit users’ access to only what was required to perform their duties, (4) encrypt sensitive data, (5) consistently audit and monitor system activity, and (6) conduct physical security reviews of its facilities. FDA conducted background investigations for personnel in sensitive positions, but weaknesses existed in other controls, such as those intended to manage the configurations of security features on and control changes to hardware and software; plan for contingencies, including systems disruptions and their recovery; and protect media such as tapes, disks, and hard drives to ensure information on them was "sanitized" and could not be retrieved after they are disposed of. The table below shows the number of GAO-identified weaknesses and associated recommendations, by control area.

<table>
<thead>
<tr>
<th>Control area</th>
<th>Number of weaknesses identified</th>
<th>Number of recommendations</th>
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</thead>
<tbody>
<tr>
<td>Access controls</td>
<td>58</td>
<td>122</td>
</tr>
<tr>
<td>Configuration management</td>
<td>23</td>
<td>37</td>
</tr>
<tr>
<td>Contingency planning</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Media protection</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>87</td>
<td>166</td>
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These control weaknesses existed, in part, because FDA had not fully implemented an agency-wide information security program, as required under the Federal Information Security Modernization Act of 2014 and the Federal Information Security Management Act of 2002. For example, FDA did not

- ensure risk assessments for reviewed systems were comprehensive and addressed system threats,
- review or update security policies and procedures in a timely manner,
- complete system security plans for all reviewed systems or review them to ensure that the appropriate controls were selected,
- ensure that personnel with significant security responsibilities received training or that such training was effectively tracked,
- always test security controls effectively and at least annually,
- always ensure that identified security weaknesses were addressed in a timely manner,
- fully implement procedures for responding to security incidents.

Until FDA rectifies these weaknesses, the public health and proprietary business information it maintains in these seven systems will remain at an elevated and unnecessary risk of unauthorized access, use, disclosure, alteration, and loss.

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