



Office of the Chief
Records Officer for the
U.S. Government

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July 11, 2022

Tiffany Branch
Agency Records Officer
Food and Drug Administration
1350 Piccard Drive, 410M
Rockville, MD 20850

Dear Tiffany Branch,

The National Archives and Records Administration (NARA) received an allegation of unauthorized disposition of Center for Drug Evaluation and Research (CDER) records. This allegation indicated that an information technology (IT) system, Appian, used for the Newly Identified Safety Signal (NISS), does not retain records documenting a full audit trail. When data in the system is entered or updated, only the date and username of the last person to touch the record is saved. Records documenting what was changed (such as the severity or related drugs) and the information on the previous modification (time and username) are deleted or overwritten with each new update.

36 CFR 1236.10 requires agencies to incorporate controls into electronic information systems to ensure a full and accurate representation of agency transactions and activities. NARA requests that the Food and Drug Administration (FDA) and CDER investigate this allegation further and provide a comprehensive report within 30 days in accordance with 36 CFR 1230.16. In your report, please identify all approved disposition authorities related to NISS and CDER's central database, Appian.

Thank you for your attention to this matter. If you wish to discuss further, please do not hesitate to contact me at Laurence.Brewer@nara.gov.

Sincerely,

A handwritten signature in blue ink that reads "Laurence v. Brewer". The signature is written in a cursive style with a large initial 'L' and a distinct 'v.' before the last name.

LAURENCE BREWER
Chief Records Officer
for the U.S. Government

Cc: Jacqlyn Smith-Simpson, Acting Department Records Officer