



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

Sent Via Email. No Hard Copy to Follow.

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, flowing style.

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

Cc: Jacqlyn Smith-Simpson, Acting Department Records Officer



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November 21, 2022

Tiffany Branch
Agency Records Officer
Food and Drug Administration
1350 Piccard Drive, 410M
Rockville, MD 20850
tiffany.branch@fda.hhs.gov

Dear Tiffany Branch,

The National Archives and Records Administration (NARA) received the Food and Drug Administration's (FDA) report dated September 7, 2022, regarding the allegation of unauthorized disposition of the Center for Drug Evaluation and Research (CDER) records.

FDA's report stated that an investigation into this allegation was conducted and findings cannot substantiate the allegations that the information technology (IT) system, Appian, used for the Newly Identified Safety Signal (NISS), does not retain records documenting a full audit trail.

FDA's report confirms that any changes made in this system are documented in an audit trail, which includes the field that was changed, the name of the person making the change, the date and time of the change, and the page where the field is present. All previously entered data into the system remains intact.

Additionally, allegations regarding changes to "severity" or "related drugs" being deleted or overwritten when updates are made within the system is inaccurate because the field "severity" does not exist and the field "related drugs" can never be changed or deleted once a NISS is opened within the system.

Finally, on October 12, 2022, the CDER records management team and Appian system owners facilitated a live demonstration for NARA of how the system operates when changes are made further confirming the system functionalities described above.

Based on the information provided and the live demonstration, NARA considers the allegations unfounded. FDA has satisfied the requirements of 36 CFR 1230.14(a) and this matter is now closed. If you have any concerns, please contact me at laurence.brewer@nara.gov.

Sincerely,

A handwritten signature in blue ink that reads "Laurence M. Brewer". The signature is written in a cursive, flowing style.

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

cc: Jacqlyn Smith-Simpson
Acting Department Records Officer
Jacqlyn.Smith@hhs.gov