



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

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December 5, 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 an allegation of unauthorized disposition of Center for Drug Evaluation and Research (CDER) records.

This allegation relates to an electronic recordkeeping system, CDER Informatics Platform - Panorama, which is used for managing the Abbreviated New Drug Application (ANDA) process. The allegation states that auditing information regarding the review and assessment of generic drugs is not being captured in its entirety.

36 CFR 1236.10 requires agencies to incorporate controls into electronic information systems to ensure a complete 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 the required report within 30 days in accordance with 36 CFR 1230.16. In your report, please identify all approved disposition authorities related to the ANDA process and CDER Informatics Platform - Panorama.

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,

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

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



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January 30, 2023

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 January 9, 2023, regarding the allegation of unauthorized disposition of the Center for Drug Evaluation and Research (CDER) records associated with the CDER electronic recordkeeping system, Informatics Platform - Panorama.

FDA's report indicates that Panorama provides real time collaboration and communication during the Abbreviated New Drug Applications (ANDA) review process. This includes the capture of regulatory submission status data changes within a viewable audit history for all ANDA applications.

The report illustrated and confirmed that any changes made within 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 is viewable to system users on the "updates tab." Additionally, all previously entered data in the system remains intact.

Based on the information provided NARA considers this unauthorized disposition allegation 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 R. Brewer". The signature is written in a cursive, flowing style.

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

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