



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

Sent Via Email. No Hard Copy to Follow.

February 4, 2025

Tiffany Branch
Food and Drug Administration
Department of Health and Human Services
1350 Piccard Drive, 410M
Rockville, MD 20850

Dear Ms. Branch,

The National Archives and Records Administration (NARA) received an allegation of unauthorized disposition of federal records. This allegation indicates that the Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) improperly disposed of agency records responsive to two freedom of information act (FOIA) requests. One FOIA request sought the completed FDA-2579 form notifying FDA of the assembly of the Philips Brilliance 10-Slice CT Scanner at St. John's Riverside Hospital, estimated to be assembled in 2005. The second FOIA request sought the completed FDA Form-2579 notifying FDA of the assembly of the FEI No. 1000091681 CT Scanner at St. John Riverside Hospital.

FDA CDRH's response to both FOIA requests indicated that no responsive records could be located and a subsequent FOIA request sought all processing notes, search slips, and internal communications pertaining to the second FOIA request. The allegation indicates that responsive documents to the third request revealed FDA CDRH had challenges accessing the CDRH Center Tracking System (CTS) database and the "2579 Universe" database, which held records responsive to both FOIA requests. Additionally, the allegation asserts that FDA CDHR "appears to have carried out the premature deletion of FDA Form-2579 reports of assembly for devices that are still in operation, in violation of Item 6.4.2 of NARA RCS NI-088-08001."

In accordance with 36 CFR 1230.16(b), NARA is requesting the FDA investigate this allegation and provide a report within 30 calendar days. If it is determined that an unauthorized disposition of records has occurred, the report should include the following information:

- A complete description of the records with volume and dates if known and any applicable NARA approved disposition authority number;
- The office maintaining the records;
- A statement of the exact circumstances surrounding the removal, defacing, alteration, or destruction of records;
- A statement of the safeguards established to prevent further loss of documentation; and
- Details of the actions taken to salvage, retrieve, or reconstruct the records.

If it is determined that there has been no unauthorized disposition, please provide sufficient documentation to support that finding. Your attention to this matter is greatly appreciated. If you have any questions or wish to discuss further, please contact the Records Management Oversight and Reporting Program by email at UnauthorizedDisposition@nara.gov.

Sincerely,

A handwritten signature in black ink that reads "William Fischer". The signature is written in a cursive, slightly slanted style.

WILLIAM FISCHER
Chief Records Officer
for the U.S. Government (Acting)

Enclosure:
2025-01-15_UD-2025-0025_RUD-att.pdf

Cc:
Susan Little
Department Records Officer