REQUEST FOR RECORDS DISPOSITION AUTHORITY

(See Instructions on reverse)

TO: NATIONAL ARCHIVES and RECORDS ADMINISTRATION (NIR)
WASHINGTON, DC 20408

1. FROM (Agency or establishment)
Department of Health and Human Services

2. MAJOR SUBDIVISION
Food and Drug Administration

3. MINOR SUBDIVISION
Center for Devices and Radiological Health

4. NAME OF PERSON WITH WHOM TO CONFER: Seung Ja Sinatra

5. TELEPHONE: (301) 827-4274

LEAVE BLANK (NARA use only)

JOB NUMBER: N1-088-03-2

DATE RECEIVED: 10-16-2002

NOTIFICATION TO AGENCY

In accordance with the provisions of 44 U.S.C. 3303a the disposition request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10.

DATE: 8-4-03

ARCHIVIST OF THE UNITED STATES: John W. Carlin

6. AGENCY CERTIFICATION

I hereby certify that I am authorized to act for this agency in matters pertaining to the disposition of its records and that the records proposed for disposal on the attached ____ page(s) are not now needed for the business of this agency or will not be needed after the retention periods specified; and that written concurrence from the General Accounting Office, under the provisions of Title 8 of the GAO Manual for Guidance of Federal Agencies,

[X] is not required; [ ] is attached; or [ ] has been requested.

DATE	SIGNATURE OF AGENCY REPRESENTATIVE	TITLE
OCT 10 2002	A. P. Barnes, Jr. A. P. Barnes	HHS Records Officer

7. ITEM NO.	8. DESCRIPTION OF ITEM AND PROPOSED DISPOSITION	9. GRS OR SUPERSEDED JOB CITATION	10. ACTION TAKEN (NARA USE ONLY)
1	This request reschedules records series, X-16 "Assembler Certification Forms." SEE Attached Schedule Fred Ansell, FDA General Counsel — Date: 10/2/02 Seung Ja Sinatra, FDA Records Officer — Date: 9/27/02	NC 1-88-78-1	

115-109 NSN 7540-00-634-4604 **STANDARD FORM 115** (REV. 3-91) (CDC Adobe Acrobat 5.0 Electronic Version, 8/2001)
PREVIOUS EDITION NOT USABLE
Prescribed by NARA
36 CFR 1228

Created by Electronic Document Services/USDHHS: (301) 443-2454

EF

Sent copies to Agency, NWMW

X-16 X-Ray Assembler Certification Reports Program
(Supersedes NC 1-88-78-1, X-16)
N1-088-03-2

Includes program related records and certification reports or forms (e.g. FDA Form 2579, etc.) that are sent to the FDA, within 15 days following the completion of an assembly by an assembler who installs one or more certified components of a diagnostic x-ray system. The report is the assembler's certification that the components installed are of the type called for by regulations, and they were assembled, adjusted, tested in accordance with the manufacturer's instructions and meets all applicable performance requirements.

Two copies (original and copy) of the reports are submitted to the Office of Compliance, Center for Devices and Radiological Health (CDRH). Upon receipt, original paper copies are sent to the FDA district field offices. Access is restricted to the Office of Compliance, CDRH.

1. **Program Administrative Records**
   Operational procedures, internal instructions, quality assurance reports, and related records.

   DISPOSITION: **TEMPORARY**. Cut off when superseded or obsolete. Transfer to FRC 1 year after cut off. Destroy 6 years after cut off.

2. **Certification Reports or Forms** (e.g. FDA Form 2579)
   A. Original reports or forms.
   Sent to and maintained by the FDA District Field Offices.

   1). Reports without problems in inspection.
   DISPOSITION. **TEMPORARY**. Cut off annually. Destroy 6 years after cut off.

   2). Reports with problems in inspection.
   DISPOSITION: **TEMPORARY.** Place in other appropriate records series file and apply authorized DISPOSITION for that record item.

   B. Copies of the reports or forms.
   Used for scanning, report checklist for entering the information into the tracking database, and duplicate copies made to produce quality image that are maintained by the Office of Compliance, CDRH.

   DISPOSITION: **TEMPORARY**. Destroy immediately upon verification of successful data entry and imaging by quality control.

3. **X-Ray Assembler Certification Tracking Database**

A. Master Data Files.
Data taken from certificate reports or forms and any additional information, notations, or analyses that are directly entered into the tracking database. Includes data fields such as assembler's name, product, date assembled, and other related information. Also used for historical trend analysis.

DISPOSITION: **TEMPORARY.** Cut off annually. Delete or destroy when superseded or obsolete, or maintain records for as long as law mandates the program.

B. Output Records
Printed or electronic reports generated in response to ad hoc queries by FDA personnel comprising information extracted from the tracking database by one or more data fields.

DISPOSITION: **TEMPORARY.** Destroy or delete when FDA determines that they are no longer needed for administrative, legal, audit, or other operational purposes. Or, place in other appropriate records series file and apply authorized disposition for that record item.

4. X-Ray Assembler Certification Imaging System.

A. Image Files (PDF, TIFF, or other imaging formats). Imaged in batches based on imaging number, date, etc.

DISPOSITION: **TEMPORARY.** Cut off annually. Destroy/delete 6 years after cut off.

B. Output Records
Printed or electronic image files generated in response to ad hoc queries by FDA personnel.

DISPOSITION: **TEMPORARY.** Destroy or delete when FDA determines that they are no longer needed for administrative, legal, audit, or other operational purposes. Or, place in other appropriate records series file and apply authorized disposition for that record item.

5. System Documentation
Systems specification, user guides, and records relating to scanning or tracking systems operation.

DISPOSITION: **TEMPORARY.** Destroy or delete when superseded or obsolete.

6. Backups of Files
Electronic copies considered by FDA to be Federal records, of the X-Ray assembler database and image files and retained in case the x-ray assembler

database or image files are damaged or inadvertently erased.

DISPOSITION: **TEMPORARY**. Delete when the identical records have been deleted, as authorized by this schedule, or when replaced by a subsequent backup file.

7. E-mail and Word Processing System Copies

Electronic copies of records that are created on electronic mail and word processing systems and used solely to generate a record-keeping copy of the records covered by the other items in this schedule. Also includes electronic copies of records created on electronic mail and word processing systems that are maintained for updating, revision, or dissemination.

A. Copies that have no further administrative value after the record-keeping copy is made. Includes copies maintained by individuals in personal files, personal electronic mail directories, or other personal directories that are used only to produce the record-keeping copy.

DISPOSITION: **TEMPORARY.** Destroy/delete within 180 days after the record keeping copy has been produced.

B. Copies used for dissemination, revision, or updating that are maintained in addition to the record-keeping copy.

DISPOSITION: **TEMPORARY.** Destroy/delete when dissemination, revision, or updating is completed.