REQUEST FOR RECORDS DISPOSITION AUTHORITY

(See Instructions on reverse)

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

LEAVE BLANK (NARA use only)
JOB NUMBER: N1-088-02-7
DATE RECEIVED: 11/26/01

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: Marilyn Flack

5. TELEPHONE: (301) 594-3661

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request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10.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: 9-24-02

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 3 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,

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

DATE	SIGNATURE OF AGENCY REPRESENTATIVE	TITLE
NOV 1 2001	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 GRS OR SUPERSEDED JOB CITATION	10.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)
Item 1	Medical Product Surveillance Network (MedSun) Pilot Project Files SEE ATTACHED SCHEDULE Elena N. Broder-Feldman 10/29/01 Elena Broder-Feldman, FDA Office of Chief Counsel Seung Ja Sinatra 10/29/01 Seung Ja Sinatra, FDA Records Officer		

115-109

NSN 7540-00-634-4064
PREVIOUS EDITION NOT USABLE

STANDARD FORM 115 (REV. 3-91)
Prescribed by NARA
36 CFR 1228

SF Copies sent to Agency, NWMW

Medical Product Surveillance Network (MedSun) Pilot Project

The Medical Product Surveillance Network (MedSun) is a pilot project operated by the Center for Devices and Radiological Health, Food and Drug Administration. MedSun collects mandatory reports of medical device related deaths and serious injuries, as well as voluntary reports of device-related minor injuries and malfunctions that are reported to the FDA by device user facilities participating in the pilot.

In the case of mandatory reports, all information contained in the source documents is incorporated into the MedSun database. In the case of voluntary reports, information contained in the source documents that could identify the facility or the facility reporter, are excluded from the database upon request from the user facility.

1. MedSun Pilot Project Files

   A. Includes general correspondence and routine administrative files.

   Disposition: **TEMPORARY.** Cut off annually. Destroy 1 year after cut off.

   B. Includes records such as pilot final planning documents, budget files, project/contract management files, and monthly and annual reports.

      (1.) Official record keeping copy kept in Contract Management Office.

      Disposition: **TEMPORARY.** Destroy 6 years and 3 months after end of contract. (GRS 3, item 3.)

      (2.) All other copies.

      Disposition: **TEMPORARY.** Destroy at end of contract, or when no longer needed for reference purposes, whichever is sooner.

2. Input Source Records

   A. Mandatory reports of a death or serious injury.
   Reports submitted on paper by facsimile or mail, transcribed to paper after submission by telephone, or entered directly into MedSun database via Internet.

   Disposition: **TEMPORARY.** Destroy paper source documents after all data elements are entered into MedSun database and successful entry is verified through quality control.

   B. Voluntary report of a minor injury or "close-call" event.

      (1.) Reports submitted on paper by facsimile or mail, transcribed to paper after submission by telephone, or entered directly into MedSun

final version approved 5/21/02 email from S.J. Smith (FDA)

database via Internet, in which the facility does not request that its facility identifiers be excluded.

Disposition: **TEMPORARY.** Destroy paper source documents after all data elements are entered into MedSun database and successful entry and verification are completed through quality control.

(2.) Reports submitted on paper by facsimile or mail, transcribed to paper by submission by telephone, or entered directly into MedSun database via Internet, in which the facility requests that its facility identifiers be excluded.

Disposition: **TEMPORARY.** Destroy paper source documents after all data elements (except for facility and reporter identifying information) are entered into MedSun database and successful entry and verification are completed through quality control.

3. Data Files

Includes data for each reported adverse event from Input Records (as described above) and any additional information, notations, or analysis that are directly entered into the database by FDA personnel and contractors.

A. Disposition: **TEMPORARY.** Cut off annually. Delete 30 years after date of cut off.

B. Facility identifiers from a voluntary report where data is submitted directly into the MedSun database via the Internet, for which the facility requests that its facility identifiers be excluded.

Disposition: **TEMPORARY.** Delete facility and reporter identifying information from the MedSun database upon successful generation of report that is used for verification of information.

4. Output Records

A. Printed reports generated in response to ad hoc queries by FDA personnel, comprising information extracted from the MedSun 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.

B. Voluntary report generated from Internet interface, where facility requests that its facility and report identifiers be excluded.

Disposition: **TEMPORARY.** Destroy immediately upon successful verification of the report.

5. System Documentation

A. Systems specification, file specifications, record layouts, user guides, input/output specifications, and records relating to system operation.

Disposition: **TEMPORARY.** Destroy or delete when superseded or obsolete, or upon authorized deletion of the MedSun database, whichever is sooner.

B. Copies of records relating to system security, including records documenting periodic audits or review, and recertification of sensitive applications, disaster and continuity plans, and risk analyses.

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

6. Backups of Files

Electronic copies considered by FDA to be Federal records, of the MedSun database and retained in case the MedSun database is 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.