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	5. TELEPHONE
Marilyn Flack	(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request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10.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	ARCHIVIST OF THE UNITED STATES
9-24-02	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 GRS OR SUPERSEDED JOB CITATION	10.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

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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 5/31/02 on behalf of 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.

revised per 5/21/02 e-mail from S. Sinatra (FDA)

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, to collect mandatory reports of medical device related deaths and serious injuries, as well as voluntary reports of device-related minor injuries and malfunctions, reported to the FDA by device user facilities[1] participating in the pilot. (User facilities that are not participating in the pilot, as well as individuals, continue to use other reporting systems, covered by existing arrangements for records filed under Device Experience Network Reports (NARA disposition authority: NC 1 88-83-2).

The MedSun pilot collects source documents primarily over the Internet to a secure website, and also accepts source documents by mail, fax, or telephone report. The Internet interface and telephone (oral) reporters use a version of the MedWatch 3500A form, modified with OMB permission to include some additional questions. Copies of the additional questions are attached. Reporters using mail or fax may use the MedWatch 3500A form or the written version of the Internet form. The MedSun pilot incorporates into a cumulative working database information from these reports, as well as additional information and analysis of the reported incidents supplied by FDA analysts and contractors. 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 may be excluded upon request from user facilities.

The system contains private and confidential information, and is maintained by the Office of Surveillance and Biometrics, Center for Devices and Radiological Health, Food and Drug Administration.

revised

1. MedSun Pilot Project Files

A. Includes general correspondence and routine files that are not needed for future reference .

Disposition: Destroy when 1 year old.

B. Includes pilot final planning documents, budget files, project/contract management files, and other project-related records.

Disposition: Cut off files annually and destroy either 6 years after end of pilot or when 10 years old, whichever is sooner.

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[1] "Device user facilities" are defined as hospitals, nursing homes, ambulatory surgical facilities, and outpatient treatment facilities which are not physician's offices. 21 U.S.C. § 360i(b)(6)(A).

3. Data Files (Database Records)

For each reported adverse event, includes data from Input Source Records (as described above) and any electronic reports directly entered into the database by the reporter via the Internet, further information gained by FDA personnel and contractors, and FDA notations and analysis.

Disposition: Delete 30 years after date of last entry regarding adverse event that is subject of that record.

4. Database Query Reports

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. The extraction process does not change the informational content of the MedSun database.

Disposition: Destroy or delete when FDA determines that they are no longer needed for administrative, legal, audit, or other operational purposes.

5. System Documentation

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

Disposition: Destroy or delete when superseded or obsolete, or upon authorized deletion of the MedSun database, or upon destruction of the output of the system if the output is no longer needed to protect legal rights, whichever is latest.

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: Destroy or delete when superseded or obsolete.

6. Backups of Files

Electronic copies, consider by FDA to be Federal records, of the MedSun database and retained in case the MedSun database is damaged or inadvertently erased:

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

report is released to FDA. (The MedSun contractor performs initial follow-up on the report before it is sent to FDA and the manufacturers.) If the reporting facility has requested that the report be deidentified, the manufacturer may work with the FDA analyst to obtain follow-up information through the MedSun contractor. This new program provides an avenue for follow-up not routinely available to manufacturers under current systems when they receive voluntary reports from FDA, from which FDA redacts reporter identities in keeping with FOIA and the agency's information disclosure regulations. Thus, the follow-up needs of the manufacturers have been incorporated into the new MedSun program.

CDRH has here proposed a records schedule to further the critical public health program described above. In only one respect is this request unusual. To encourage user facilities to submit voluntary reports, CDRH must offer the guarantee that if they request, in conjunction with voluntary reports, their identities will be used only for the limited purpose of allowing CDRH to do short term follow-up to fill out the details of the initial reports, and that those identities will not be made a part of the cumulative database of adverse events that CDRH will use to track possible problem devices. For CDRH to make this representation to pilot participants requires NARA to approve a records schedule under which CDRH will dispose of source documents that contain the reporter identities as soon as CDRH has completed its follow-up, which by policy will take place within 30 business days of the receipt of the report. In short, CDRH must have NARA permission to dispose of these voluntary report source documents before it can collect them at all, in order to test its hypothesis that offering this guarantee will improve participation over a system, like the present one, where the identities of voluntary reporters are retained along with the rest of the report.

We hope that this background material answers your questions regarding MedSun and will of course be happy to meet with you at your earliest convenience to discuss any remaining issues. Given the importance of this matter to FDA's public health and safety programs, we thank you in advance for your expedited consideration.