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	N1-088-09-2
DATE RECEIVED	12/19/08

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

2 MAJOR SUBDIVISION
Food and Drug Administration (FDA)

3 MINOR SUBDIVISION
Office of Regulatory Affairs (ORA)

4 NAME OF PERSON WITH WHOM TO CONFER	5 TELEPHONE
Seung Ja Sinatra	(301) 827-4274

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request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10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
10/2/09	Adrienne Thomas

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 12 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,

☒ is not required; ☐ is attached; or ☑ n/a has been requested ~~change made per Rec off on 8/11/09~~

DATE	SIGNATURE OF AGENCY REPRESENTATIVE	TITLE
12/16/2008		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7 ITEM NO	8 DESCRIPTION OF ITEM AND PROPOSED DISPOSITION	9 GRS OR SUPERSEDED JOB CITATION	10 ACTION TAKEN (NARA USE ONLY)
	Unless specifically stated otherwise in the description or the retention, all items are media-neutral and apply to paper, electronic, microform, or other media in which records may exist ORA and Field Program Records (Group 1 of 2) see attached Seung Ja Sinatra - FDA Records Officer — 6/19/06 Date Ann Wion - FDA Deputy Chief Counsel — 12/9/08 Date		

ORA and Field Program Records (Group 1)

File Code: Prefix = ORA/FIELD

Item No.	Records Description and Authorized Disposition	NARA Approved Citation
1	**ORA Program Management**	
1.1	**ORA Work Plan.** The work plan is a resource allocation report prepared from consolidated data by ORA, in coordination with FDA Centers and the ORA Field Services Committee, and includes annual plans and summary reports. Summary Report 1 combines FDA District and lab research functions and provides information about program/subprogram, FTE allocations and positions; Summary Report 2 provides the same information but includes a separate plan for lab research activities, Summary Report 3 provides inspection information (number of FTEs and number of inspections) for each FDA component and program. Records are maintained both in paper (before and including Sept 2002) and electronic media (since October 2002). Automated tools such as MODEL/Field Work Force Planning System (FWFPS) and Online Program Analysis System (OPAS) are used as planning and reporting tools. **Disposition: TEMPORARY.** Cutoff at end of the fiscal year in which the associated plan is completed. Delete/destroy 10 years after cutoff.	New
1.2	**ORA Accomplishment Reports.** Used as ready reference to monitor monthly accomplishments and resource expenditures in terms of hours in various levels of planned and unplanned program areas Consists of monthly reports and final monthly reports available after the fiscal year. Monthly reports are available to field offices via the Web, on off-line electronic media from 2001 to present, and on microfiche from 1970's to 2000. Online analytical processing (OLAP) tools such as OPAS and MODEL/FWFPS are used to assess performance against actual resource utilization reports using consistent decision rules **Disposition: TEMPORARY.** Cutoff at end of the fiscal year in which the associated report is completed Delete/destroy 30 years after cutoff or when no longer needed, whichever is later.	

2 State, Federal and Inter-Governmental Relations

2.1 State Commissioning Program.

The program was designed to enhance interagency cooperation and to utilize the potential of state and local officials to perform specifically designated functions as commissioned FDA officials that are subject to Federal jurisdiction, e.g., to conduct examinations, inspections and investigations; to collect and obtain samples; to copy and verify records; and to receive and review official FDA documents These functions are carried out and in one or more program areas (i e , foods, drugs, etc.).

2.1.1 Commissioning Documents.

Supersedes NC1-88-78-1 O-16

Includes correspondence, personal history statements, approvals and related documents pertaining to the commissioning of State and local officials Each commission is issued for a period of three years and can be renewed depending on the scope of the commission Records are maintained by the FDA regional offices

Certain records may contain personal information that cannot be publicly disclosed; disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations.

Disposition: TEMPORARY.
Cutoff and the end of the fiscal year after commission is revoked or expired. Delete/destroy 5 years after cutoff.

2.1.2 Nationwide List of FDA Commissions.

Provides information on name, region, State name, agency program, expiration date and other related information. It is cumulatively updated with new additions, renewals and cancellations received from various field offices, and is maintained by ORA.

Disposition: TEMPORARY.
Cutoff at end of the fiscal year when obsolete or superseded. Delete/destroy 3 years after cutoff.

2.1.3 Summary Reports of FDA Commissions.

Includes summary data of commission status prepared by FDA regions from their files of commissioning documents and submitted to ORA Contains information on additions, renewals and cancellations; used to compile and update the nationwide list of FDA Commissions

Certain records may contain personal information that

cannot be publicly disclosed; disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations.

Disposition: TEMPORARY.
Delete/destroy after the nationwide list of FDA Commissions has been updated

2.1.4 **List of FDA Commissioned CBP Personnel.**
Includes the lists of FDA commissioned CBP personnel submitted by the Customs and Border Protection (CBP), Department of Homeland Security. Certain records may contain personal information that cannot be disclosed; disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statues and FDA's implementing regulations.

Disposition: TEMPORARY.
Cutoff at the end of the fiscal year when obsolete or superseded. Delete/destroy 5 years after cutoff

2.2 **Contract and Grant Records.** **Supersedes NC1-88-78-1 O-17**
Consists of duplicate copies of documents created as part of grants and contracts issued to States, territories, and tribal governments to support FDA inspection and training requirements Record copies are maintained by the FDA Office of Shared Services.

Disposition: TEMPORARY.
Cutoff at the end of the fiscal year after the contract or grant is closed-out. Destroy/delete 5 years after cutoff.

2.3 **State Inspection Program Evaluation Files.** **New**
Consists of records that document evaluation of inspections performed by State inspectors under FDA contracts

2.3.1 **Contract Audit Activity Reports.**
Includes periodic reports submitted by field personnel to project officers (based on State responsibility assigned). The report provides contract and contractor information, summarizes audits and inspections performed during the reporting period, and provides comments on performance and accomplishments. May also include records addressing remediation of inspection deficiencies

Revised 8/27/09 APL

Disposition: TEMPORARY.
Cutoff at end of the fiscal year after the contract is completed. Delete/destroy 3 years after cutoff

2.3.2 **Inspection Service Evaluation Reports**
Includes detailed reports prepared by FDA inspectors carried out as joint or independent audits of contract-funded State or tribal inspection services Provides information such as discrepancies between what was reported and what was done as well as payment disputes. Records are maintained by the FDA field offices

Disposition: TEMPORARY
Cutoff at end of the grant/contract cycle once the contract or grant has ended. Delete/destroy 5 years after cutoff

~~2.3.3~~ ~~**Adverse Finding Memoranda.**~~ **Withdrawn 8/27/09**
~~May include adverse finding memoranda, prepared by FDA District Office personnel, which document problems and corrective action steps; related correspondence between the District and the contracting State; and a District Director assessment of the cause of the problem and the possibility of satisfactory correction and concurrence with the findings and actions by the Regional Director The memoranda becomes the foundation document for decision making and discussions between FDA and State officials.~~

~~**Disposition: TEMPORARY**~~
~~Cutoff at end of the grant/contract cycle once the grant or contract has ended. Delete/destroy 3 years after cutoff.~~

2.4 **Shelf Life Extension Program (SLEP) Records.** **New**
Includes materials on findings and outcomes of shelf life testing performed in one of the FDA certified testing labs (Detroit, Philadelphia and San Juan). Copies of a cover letter and final report are electronically sent to Department of Defense (DOD) or other requesting agencies Original analytical test records and samples are maintained at the testing lab Records date from 1985.

Certain records contain trade secrets, confidential commercial information, and other information that cannot be publicly disclosed; disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations

Under the program, FDA and DOD have an Interagency Agreement (IAG) governing the testing of pharmaceuticals for potential shelf-life extension. Record copies of the IAGs are maintained in the Office of Shared Services.

2.4.1 **SLEP Final Reports and Program Files in ORA.**

May include requests for testing, correspondence, final reports, selected portions of analytical worksheets and methodologies used for shelf life testing, copies of project reports from CDER, database reports, copies of IAGs and other related records.

Disposition: TEMPORARY. Cutoff at the end of the fiscal year when testing of an entire lot is complete. Delete/Destroy 6 years after cutoff.

2.4.2 Analytical Testing Worksheets Maintained in CDER.
Includes a complete set of analytical testing reports and project reports for shelf life extension.

2.4.2.1 Summary of the Results and Project Reports.

Disposition: TEMPORARY Cutoff at the end of the calendar year when testing of an entire lot is complete. Delete/Destroy 20 years after cutoff or when no longer needed for reference, whichever is later.

2.4.2.2 Analytical Worksheets.

Disposition: TEMPORARY. Cutoff at end of the calendar year when testing of an entire lot is complete. Delete/Destroy 10 years after cutoff.

2.4.2.3 Raw Data.

Disposition: TEMPORARY. Cutoff at end of the calendar year when testing of an entire lot is complete. Delete/Destroy 5 years after cutoff

2.5 Government-wide Quality Assurance Program (GWQAP).
Under GWQAP, FDA provides responses to requests for pre-award evaluation, to the military or to the Veterans Administration (VA), of firms bidding (or desiring to bid) on government contracts

2.5.1 GWQAP Project Files. **Supersedes NC1-88-80-2, items O-23 and R-35**
Includes materials relating to GWQAP projects such as pre-award evaluation requests, FDA's response letters along with "Quality Request Details" sent to the Defense Supply Center or VA, and other related materials.

Disposition: TEMPORARY.
Cutoff at end of the fiscal year after final action Transfer to FRC 3 years after cutoff. Destroy 7 years after cutoff

~~**2.5.2 COMTRACK Tracking System**~~ **GRS 23**

~~Used as a tracking and reporting system for pre-award evaluation status for GWQAP projects. Provides information on control number, requester, request and response dates and related tracking data.~~

Item 8

~~**Disposition: TEMPORARY.**~~
~~Delete/destroy when 2 years old or 2 years after the latest entry, whichever is applicable.~~

3 Compliance

3.1 Regulatory Notes.

Supersedes NC1-88-79-1 R-10

Notes taken by an inspector during the course of an official regulatory activity such as an inspection, investigation, sample collection, or field examination The notes may be handwritten or taken electronically. They contain a diary of the events that are part of the regulatory activity, such as what was conducted, objectionable conditions, details of sample collections and other related information. Regulatory notes should be identified with the name of the inspector/investigator and the dates they cover.

Depending on the FDA District's policy, records are maintained by the inspector/investigator, filed with the final report, or kept by the District in a separately designated secure file. If the inspector/investigator permanently leaves the District before the authorized destruction date, files in their possession are identified and maintained in the District's secure file room until available for destruction.

Certain records contain trade secrets, confidential commercial information, and other information that cannot be publicly disclosed; disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations.

Disposition: TEMPORARY Cutoff at the end of the fiscal year after date of the activity (inspection, investigation, sample collections, field exam, etc) or when determined that there is no possibility of a legal action resulting from the activity, whichever is later. Destroy/delete 10 years after cutoff.

4 Regulatory Support Activities

4.2 National Check Sample Program (NCSP).

New

The NCSP is a proficiency-testing program for chemistry, microbiology and other FDA field analyses, which is

required for maintaining accreditation for all Center and ORA regulatory laboratories. The Program is an inter-laboratory testing scheme that is designed to demonstrate uniformity of results among the laboratories, evaluate each laboratory's analytical capabilities, and assess the quality of evidence documentation with respect to regulatory actions. Each laboratory conducts sample analysis independently and then sends the results to the ORA Division of Field Science (DFS) for evaluation.

The final check sample reports and memoranda are prepared based on the analytical package submitted by each laboratory.

4.2.1 **Check Sample Analytical Packages.**
Includes FDA Form 431 (Worksheet), printouts from analytical instruments, chromatographs, spectra and other related records to show analytical findings based on the needs which vary from sample to sample Records are forwarded to individual ORA Division of Field Science Coordinators assigned within 30 days of sample receipt.

Official sample records on findings, analytical conclusions, sample classification codes and other related information are maintained in FACTS or its successor system by the lab For records retention, apply disposition authorized under "Domestic Sample Analytical Documentation

Disposition: TEMPORARY.
Cutoff at the end of the fiscal year after the Final Report is completed. Destroy/delete 3 years after cutoff

4.2.2 **Final Check Sample Reports.**
Consists of final reports and final check sample memoranda that summarize the contents of the final reports and serve as transmittal documents. Final reports include final documents with tables of data that include PT scheme, technology and/or method used, participants results, assigned value, range of acceptable results and results obtained by the issuing laboratory, together with a statistical evaluation. Record copies are maintained by the issuing office.

Disposition: TEMPORARY
Cutoff at the end of the fiscal year after the final report is completed Delete/destroy 5 years after cutoff or when no longer needed for reference, whichever is later.

4.2.3 **National Check Sample Program (NCSP) Annual Schedule.**

The annual schedule of all check samples to be performed, developed by an ad hoc committee of field representatives The schedule is used to plan sample collection and processing for the fiscal year

Disposition: TEMPORARY.
Cutoff at end of the fiscal year after the completion of check sample anaylsis Delete/Destroy 5 years after cutoff or when no longer needed for reference, whichever is later.