REQUEST FOR RECORDS DISPOSITION AUTHORITY

(See Instructions on reverse)

LEAVE BLANK (NARA use only)	
JOB NUMBER	N1-088-09-7
DATE RECEIVED	7/22/09

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 (FDA)

3 MINOR SUBDIVISION
Agency-wide

4 NAME OF PERSON WITH WHOM TO CONFER	5 TELEPHONE
Seung Ja Sinatra	(301) 796-3802

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request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10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
1 NOV 10	

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,

☑ is not required; ☐ is attached; or ☐ has been requested

DATE	SIGNATURE OF AGENCY REPRESENTATIVE	TITLE
7/20/09	Yvonne R. Wilson	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7 ITEM NO	8 DESCRIPTION OF ITEM AND PROPOSED DISPOSITION	9 GRS OR SUPERSEDED JOB CITATION	10 ACTION TAKEN (NARA USE ONLY)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. SEE attached sheet Agency-wide Program Records (Group 4) Seung Ja Sinatra - FDA Records Officer — Date: 4/17/09 Ann Wion - FDA Office of Chief Counsel — Date: 7/10/09		

Agency-wide Records (Group 4)

File Code prefix = FDA/Agency-wide

Item No	File Code	Records Description and Authorized Disposition	NARA approved citation
1		**Emergency, Incident, Outbreak Records.**	
1.1		**Emergency/Incident Management and Trace Back Files.** Records include incident related files regarding FDA regulated product that are, or may be, responsible for causing injury, illness or adverse events Records may be created and maintained by either the Office of Crisis Management at FDA Headquarters or at the center/office level. The records document responses to incidents and include information regarding activities undertaken in the early stages of investigations; analytical findings; documents, including emails, reflecting guidance and information provided to internal and external partners; preliminary findings, agency internal deliberations and decisions made by FDA Headquarters to inform incident response activities by FDA components (including the centers, the Office of Regulatory Affairs, the Office of Chief Counsel, the Office of International Programs, the Office of Public Affairs, the Office of Legislation, the Office of Management, the Office of Counter Terrorism Policy and Emerging Threats, and the Office of Food Protection), Geographic Information System (GIS) maps related to emergency response activities, and trace back files Records may be in paper or electronic format. Electronic records exist only after August 2004. Headquarters records date from 2001. Center/office level records date from 1990.	
1.1.1		**Significant Emergency/Incident Management Files** Includes the records relating to incidents that required Emergency Operations Center activation that involved intense media, public or Congressional interest. Some examples include national disaster response such as that for Hurricane Katrina; or incidents of widespread national concern such as the 2009 melamine in pet food incident and the Peanut Corporation of America incident Also includes records at the Center/office level relating to events of similar significance prior to the creation of the Emergency Operations Center in 2001. Certain records contain trade secret and confidential commercial information that may not be publicly released, 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: PERMANENT.
Cut off at end of the fiscal year after investigation is completed. Transfer in NARA approved format 10 years after cutoff

1.1.2 **Non-significant Emergency/Incident Management Files** — **Supersedes N1-088-04-5 Item 5**

Includes all other emergency/incident management and trace back files that do not rise to the level of significant.

Certain records contain trade secret and confidential commercial information that may not be publicly released, 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.
Cut off at end of the fiscal year after investigation is completed. Destroy/delete 10 years after cutoff, or when no longer needed for business or reference purposes, whichever is the latest

1.2 **Event of Interest Records (Non-FDA Regulated Products).** — **New**

Includes records documenting events of interest to the agency where the events have been determined to be associated with products not regulated by FDA

Disposition: TEMPORARY.
Cutoff at end of the fiscal year when the investigation is closed. Transfer paper records to FRC in 5-year blocks 20 years after cutoff. Delete/destroy 25 years after cutoff.

1.3 **Incident, Outbreak Reports: Weekly Status Updates** — **Supersedes N1-088-04-5 Item 6.1**

Includes reports produced weekly on the status of and major activities relating to significant incidents being acted upon by FDA at the agency level

Records have been accumulated since January 2004.

Disposition: PERMANENT.
Cut off at the end of the calendar year in which created. Transfer to the National Archives immediately after cutoff. If electronic records are transferred, they must be transferred in an NARA approved format.

1.4 **Incident, Outbreak Reports: Other Reports** — **Supersedes N1-088-04-5 Item 6.2**

Includes annual summary reports regarding all major outbreaks associated with FDA regulated products; reports on each outbreak (i.e. situation reports), and reports submitted by a center/office to the Office of the Commissioner, including reports submitted to the Office of the Commissioner in response to Congressional inquiries.

Disposition: **TEMPORARY.**
Cutoff at end of the fiscal year after report has been submitted. Delete/destroy 30 years after cutoff

1.5 **Emergency Operations Databases.**
Systems used to track and compile information regarding incidents/outbreaks associated with FDA regulated products and events of interests.

1.5.1 **Emergency Operations Network Incident Management System (EON IMS) Data Files.**
Records include incident data (e.g., product name, details regarding source of incident report, date information related to incident received by FDA, weekly status report, the center responsible for regulating the product at issue, significant FDA activities related to incident response), incident description, and internal comments regarding the incident, as well as other related data

This does not include incident records (documents, e-mail, etc) covered by 1 1 1 or 1 1 2 that may be maintained in the EON IMS system. This item only covers the system data.

Certain records contain trade secret and confidential commercial information that may not be publicly released, 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.

1.5.1.1 **EON IMS Data Files: Data Files for Significant Emergency/Incident Management Files**

Disposition: **PERMANENT.**
Cut off at end of the fiscal year after investigation is completed. Transfer to NARA 10 years after cutoff.

1.5.1.2 **EON IMS Data Files: Data Files for Non-significant Emergency/Incident Management Files**

Disposition: **TEMPORARY.**
Cutoff at end of the fiscal year after investigation is completed. Delete/destroy with related records 30 years after cutoff, or when no longer needed for business or reference purposes, whichever is later.

1.5.2 **Incident/Outbreak Data Files Maintained in Center/Office.**
Includes identification number, year of outbreak, agent involved, vehicle/product involved, product source, total number of illnesses, number of deaths/hospitalizations, date first illness was reported, and date of first email about the outbreak, as well as

related data and supporting information.

Includes the following:
CFSAN Outbreak Surveillance Database.

Disposition: TEMPORARY.
Cutoff at end of the fiscal year when the investigation is closed. Delete/destroy 30 years after cutoff, or when no longer needed for business or reference purposes, whichever is the latest.

1.5.3 **EON IMS Output Records: Alert and Notifications.**
Notifications sent to key agency officials to ensure timely awareness of public health issues.

Disposition: TEMPORARY.
Cutoff at end of the fiscal year after notification has been issued. Delete/destroy 3 years after cutoff.

~~1.5.4~~ ~~**Ad-hoc Reports.**~~ **GRS 20**
~~Includes ad-hoc and status reports~~ **Items 12 and 16**

~~**Disposition: TEMPORARY.**~~
~~Delete/destroy when superseded or obsolete, or when no longer needed for reference purposes, whichever is the latest.~~

2 **Combination Products Program Records.** **New**
Includes records related to classification of a product as a drug, device, biologic, or combination product, as well as records related to assignment of these products to a lead center for Agency review.

Certain records contain trade secret and confidential commercial information that may not be publicly release; 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.

2.1 **Request for Designation Records.**
Records include Requests for Designation from manufacturers, records and correspondence documenting review of Requests for Designation, determinations of classification and assignment of products subject to Requests for Designation since 1992, and redacted Requests for Designation.

Disposition: TEMPORARY.
Cutoff at end of the calendar year in which the product has been designated Delete/destroy 75 years after cutoff.

2.2 **Designation Data: Database Records.**
Used to track all Requests for Designation and review status. Data is maintained by the Center for Devices and Radiological

Health (CDRH) in the Center Tracking System (CTS), or its successor system, Data fields include product name, manufacturer name, document identification number, determination date, and product classification and assignment, as well as other related information.

Disposition: TEMPORARY.
Cutoff at end of the calendar year in which the product has been designated. Delete/destroy 75 years after cutoff.

~~2.3~~ ~~**Designation Data: Ad-hoc reports**~~ **GRS 20**
~~Generated from the Center for Devices and Radiological Health (CDRH) in the Center Tracking System (CTS), or its successor system~~ **Items 12 or 16**

~~**Disposition: TEMPORARY.**~~
~~Delete/destroy when superseded or obsolete, or when no longer needed for administrative or operational purposes, whichever is latest.~~