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	N1-088-09-1
DATE RECEIVED	9/8/09

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

2 MAJOR SUBDIVISION
Food and Drug Administration (FDA)

3 MINOR SUBDIVISION
Agency-wide and CDRH

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request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10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
25-Jan-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
9/1/09	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7 ITEM NO	8 DESCRIPTION OF ITEM AND PROPOSED DISPOSITION	9 GRS OR SUPERSEDED JOB CITATION	10 ACTION TAKEN (NARA USE ONLY)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 User Fee Files CDRH Image 2000 Seung Ja Sinatra 8/26/09 Seung Ja Sinatra - FDA Records Officer Date		

Agency-wide Records (User Fee Files)

File Code prefix = FDA

Item No	File Code	Records Description and Authorized Disposition	NARA approved Citation
1		**User fee Files.** Records relating to Fees charged either for services provided by FDA to industries or annual fees relating to products currently on the market under the following regulations· Tobacco, Prescription Drug User Fee Act (PDUFA), Medical Device User Fee and Modernization Act (MDUFMA), Mammography Quality Standards Act (MQSA), Export Reform and Enhancement Act (EREA), Animal Generic Drug User Fee Act (AGDUFA), Animal Drug User Fee Act (ADUFA), and Color certification.	New
1.1		**User Fee Files maintained in the OFM.** Files include invoices, cover sheets, payment receipts, copies of deposit tickets, tobacco market share records, Annual Reports to the Congress, 5-year plans, and other related records, that are maintained agency-wide in the Office of Financial Management (OFM). Records copies from 2001 are electronically maintained; and files before 2001 in paper 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.** Cutoff at end of the fiscal year after the completion of the 5-year User Fee Program cycle. Delete/destroy 75 years after cutoff, or when no longer need for administrative, legal, or reference purposes, whichever is the latest.	
1.2		**User Fee Data Maintained by Centers.** Waivers to the user fees and some information used to compile the Annual Reports to Congress are submitted to the Office of Financial Management, while being maintained by the Centers 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.** Cutoff at end of the fiscal year after the completion of the 5-year User Fee Program cycle. Delete/destroy 70 years after cutoff, or when no longer need for administrative, legal, or reference purposes, whichever is the latest.	

1.3 **User Fee Systems**

In addition to maintaining electronic records of invoices and payment receipts since 2001, it provides a tracking capability.

~~1.3.1~~ ~~**Input Records.**~~ **GRS 20**
~~Hard copy documents used for scanning.~~ **Item 2a(4)**

~~**Disposition: TEMPORARY.**~~
~~Destroy after the information has been converted to an electronic medium and verified, when no longer needed for legal or audit purposes or to support the reconstruction of, or serve as a back up to the electronic records, whichever is later.~~

1.3.2 **User Fee Database Records.**

Tracks cover sheet number, invoice number, firm name, payment receipt number/date, and related information.

For electronic documents, apply records retention authorized under Item 1.1 or 1.2.

Disposition: TEMPORARY.
Cutoff at end of the fiscal year in which received. Delete/destroy 75 years after cutoff, or when no longer need for administrative, legal, or reference purposes, whichever is the latest.

~~1.3.3~~ ~~**User Fee Output Records.**~~
~~Includes ad hoc reports generated by authorized users.~~ **GRS 20 Items 12 and 16**

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

~~CDRH Electronic System (IMAGE 2000)~~

~~**File Code prefix = CDRH**~~

~~Item No~~	~~File Code~~	~~Records Description and Authorized Disposition~~	~~NARA approved Citation~~
~~2~~		~~**Image 2000 (I2K).**~~ ~~Repository of electronic documents for regulatory submissions and administrative records for medical device submissions, MedWatch reports, and Radiological Health reports.~~ ~~Supports pre- and post-marketing approval process by electronically storing regulatory submissions for medical devices. It covers documents from 1974 to present.~~	~~New~~

This system contains both electronic documents and limited data about the documents.

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.

.

2.1 **I2K Database Records.** **WITHDRAWN 11/6/09**

In addition to electronic records stored in the repository, includes metadata associated with the stored documents such as file size, number of pages, submission number, folder type (PMN, PMA, MDR, etc.).

Electronic documents are disposed of in accordance with authorized records retention schedules under appropriated subject series.

Disposition: TEMPORARY.

Maintain metadata until all documents are migrated into a successor system. Delete/destroy after verification of successful migration or when no longer needed for operation, which ever is later.

2.2 **I2K Output Records** **WITHDRAWN 11/6/09**

Copies of the documents stored in the repository used for reference.

Disposition: TEMPORARY.

Delete/destroy when the agency determines that they are no longer needed for administrative, legal, audit or other operational purposes.