REQUEST FOR RECORDS DISPOSITION AUTHORITY

(See Instructions on reverse)

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
Center for Drug Evaluation and Research (CDER)

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

LEAVE BLANK (NARA use only)

JOB NUMBER
N1-088-06-4

DATE RECEIVED
8-10-2006

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request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10.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
9/18/06	[signature]

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 ____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
8/2/06	[signature]	FDA 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 GRS OR SUPERSEDED JOB CITATION	10.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.~~ Advertising and Promotional Labeling Materials Review Files: see attached		

NSN 7540-00-634-4604 **STANDARD FORM 115** (REV. 3-91) (CDC Adobe Acrobat 5.0 Electronic Version, 8/2001)
PREVIOUS EDITION NOT USABLE Prescribed by NARA
36 CFR 1228
Created by Electronic Document Services/USDHHS: (301) 443-2454

SA Copies Sent To Agency, NWMD, NWME, NWMW EF

4 5500 **Advertising and Promotional Labeling Materials Review Files.**
Includes advertising materials or promotional labeling items.

4.1 5510 **Advertising and Promotional Labeling Materials.**
Includes Form FDA 2253, "Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use", and accompanying advertising and promotional labeling materials that were submitted by manufacturers or sponsors as required by 21 CFR 314.81 (b)(3)(i) and 21 CFR 601.12 (f)(4) at time of initial publication or initial dissemination.

(1) **Disposition: TEMPORARY.** **Supersedes**
Cut off at the end of the calendar year in which received. Destroy/delete 2 years after cutoff or when no longer needed, whichever is later. **NC1-88-81-2 RCS, D-29**
This disposition instruction applies to all media and formats UNTIL these records are maintained in an electronic recordkeeping system.

4.2 5520 **All Other Advertising and Promotional Labeling Materials.**

Commonly referred to as "red jackets". Includes all other advertising and promotional labeling materials (e.g. requests for advisory on draft advertising and promotional labeling materials, complaints, internal CDER documents related to the subject, advisory comments from FDA to industry, enforcement letters along with the violative materials). Records contain confidential information and FOIA restrictions for public access will apply.

5521 **Closeout Packet**

Closeout packet includes warning letters and untitled letters, the violative piece, any correspondence, and a closeout letter. Records contain confidential information and FOIA restrictions for public access will apply.

(2) **Disposition: PERMANENT.** **Supersedes**
Cut off at the end of the calendar year in which the last action took place. Transfer to NARA 30 years after cutoff or when no longer needed, whichever is later. **NC1-88-81-2 RCS, D-29**

5522 **All other material.**

(3) **Disposition: TEMPORARY** **Supersedes**
Cut off at the end of the calendar year in which the last action took place. Destroy 30 years after cutoff or when no longer needed, whichever is later. **NC1-88-81-2 RCS, D-29**
This disposition instruction applies to all media and formats UNTIL these records are maintained in an electronic recordkeeping system.

4.3 5530 **Advertising Materials Review Tracking Systems.**
Advertising Management Information System (ADMIS) tracks over 50,000 advertising and promotional labeling materials per year for CDER regulated products (i.e. materials submitted on FDA Form 2253). If violative, a flag is set to indicate that case has been transferred to MACMIS.

Marketing, Advertising and Communications Management Information System (MACMIS) tracks incoming submissions (i.e. all submissions except those submitted on FDA Form 2253) and outgoing correspondence. It tracks approximately 250 issues per year. Contains confidential information and FOIA restrictions apply.

4.3.1 5531 ~~Input Records.~~
~~ADMIS: Data is input from FDA Form 2253 and accompanying advertising and promotional labeling materials.~~
~~MACMIS: Data is input from cover letter and other related materials.~~

~~**Disposition: TEMPORARY.**~~
~~Apply disposition instructions authorized under appropriate records series.~~

4.3.2 5532 Data Files.
ADMIS: Data fields include information such as ADMIS ID number, product, manufacturer, date received, type of material, reviewers, comments, completion date, field used to flag violative case and NDA numbers.

MACMIS: Data taken from the submissions described above includes information such as MACMIS ID number, company, type of material, reviewers, letter date, status of case, dates for closure, and NDA numbers.

(4)

Disposition: TEMPORARY.
Delete when no longer needed for operational or administrative purposes.

4.3.3 5533 Output Records.
Ad-hoc reports generated as needed.

(5)

Disposition: TEMPORARY.
Destroy/delete when superseded/obsolete, or when no longer needed for administrative or reference purposes, whichever is later.
This disposition instruction is media neutral, it applies to all media and formats.

4.3.4 5534 ~~System Documentation.~~
~~Includes system documentations on data fields/codes, relationships to data and data entry procedures .~~

~~**Disposition: TEMPORARY.**~~ ~~**GRS 20**~~
~~Destroy/delete when superseded or obsolete, or upon authorized deletion of the related master file or system, whichever is later.~~ ~~**Item 11a**~~

4.3.5 5535 ~~Backups. Performed as part of COMIS backup procedures or its successor system. Refer to disposition instructions under~~

~~**Disposition: TEMPORARY.**~~ ~~**GRS20**~~
~~Delete when the identical records have been deleted, or when replaced by a subsequent backup file.~~ ~~**Item 8B**~~