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	N1-088-09-5
DATE RECEIVED	2/24/09

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request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10

1 FROM (Agency or establishment)	
Department of Health and Human Services	
2 MAJOR SUBDIVISION	
Food and Drug Administration (FDA)	
3 MINOR SUBDIVISION	
Center for Food Safety and Applied Nutrition (CFSAN)	
4 NAME OF PERSON WITH WHOM TO CONFER	5 TELEPHONE
Seung Ja Sinatra	(301) ~~827-4274~~ 796-3802

DATE	ARCHIVIST OF THE UNITED STATES
05Jan10	

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 10 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
2/20/09	Claire Parker	Acting, 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7 ITEM NO	8 DESCRIPTION OF ITEM AND PROPOSED DISPOSITION	9 GRS OR SUPERSEDED JOB CITATION	10 ACTION TAKEN (NARA USE ONLY)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. CFSAN Program Records. Group 1 (see attached) Seung Ja Sinatra Seung Ja Sinatra - FDA Records Officer — 2/7/06 Date Ann Wion Ann Wion - FDA Deputy Chief Counsel — 2/4/09 Date		

CFSAN Program Records (Group 1)

File Code Prefix = CFSAN

Item No.	File Code	Records Description and Authorized Disposition	NARA Approved Citation
1		**Premarketing Submissions for Food Products.**	
1.1		**Temporary Marketing Permits.** Includes applications for permits, as specified in 21 CFR 130 17, to market foods deviating from definitions and standards of identity in 21 CFR Parts 131-169, supporting documentation such as information on processing and components of food products, copies of permits, correspondence, and copies of citizen petitions, as well as related materials Covers records from 1939 to present 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. Public versions of the documents maintained by Dockets are subject to Dockets records control schedules. **Disposition: TEMPORARY.** Cutoff at the end of the calendar year after expiration of permit, extensions, or change of standard of identity. Delete/destroy when no longer needed for operational purposes, or 20 years after cutoff, whichever is later.	**Supersedes NC1-88-78-1 F12 & F13**
~~1.2~~		~~**Program Subject Files.**~~ ~~Includes mission oriented specific subject files such as studies and reports of short-term or long-range significance or with historical values~~	**Approved in N1-088-07-2**
~~1.2.1~~		~~**Substantive Program Subject Files**~~ ~~Includes materials with inherent evidential and informational values vital for the primary use in developing an agency history. These records furnish the researcher with the insight, planning, organizational structure, functions, and overall agency direction Supersedes in part NC 1-88-78-1, Item 1a.~~ ~~**Disposition: PERMANENT.** Cutoff at end of the calendar year after the final action or when no longer needed to conduct current operations Transfer paper records to FRC after cutoff Transfer records to NARA 20 years after cutoff.~~	**Supersedes in part NC1-88-78-1, item 1a** **Item previously approved under N1-088-07-2, item 3.1.1**
~~1.2.2~~		~~**Non-Substantive Program Subject Files.**~~ ~~Covers files relating to FDA mission subject areas with limited value Includes correspondence, reports with short-term value,~~	**Supersedes in part NC1-88-84-3,**

~~unfinished reports that may be used for future studies, current issues, and other informational materials and non-substantial program records.~~

Item 3; NC1-88-78-1, Items F53a, F53b, F53c, F53d, F55

~~Includes the following CFSAN records, but not limited to:~~
~~Food Additive Extension (FAX, FAY, FAZ)~~
~~GRAS Review Monographs (GRM)~~
~~Precedent Records~~
~~Published and Unpublished Studies~~
~~Opinion Letter Files (OLF)~~
~~Subject Reference Files (SBJ)~~

Item previously approved under N1-088-07-2, item 3.1.2

~~**Disposition: TEMPORARY.** Destroy/delete when 30 years old or when no longer needed for agency business after retrospective review, whichever is later.~~

1.3 **Food Applications Regulatory Management System (FARM).**
FARM is an electronic information management system designed to support electronic processing, assignment, notification, review, maintenance and reporting for food ingredients submissions. It provides analytical and search tools to manage food and color additive petitions, notifications, consultations, product master lists, New Dietary Ingredient (NDI) notices, as well as other Office of Nutrition Labeling and Dietary Supplement documents It also provides analytical and search tools to manage Food Allergen Labeling & Consumer Protection Act (FALCPA) petitions to support safety reviews, evaluations and decisions. It supports electronic submissions, FOI requests and communications disclosing information to industry and consumers. 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.

~~1.3.1~~ ~~**FARM: Input Records.**~~
~~Includes data from industry submissions of: premarket consultations, petitions, and notifications; Threshold of Regulation (TOR) letters, and precedent files with substantial historical value, as well as other related records such as FOI requests and general correspondence from industry and others. Includes data from both electronic submissions directly entered into the system and paper submissions scanned into the system.~~

GRS 20, Item 2a4

~~For precedent files, apply disposition authorized for that series.~~

~~**Disposition: TEMPORARY.**~~
~~Destroy after the information has been converted to an electronic medium and verified, when no longer needed for legal or audit purposes.~~

1.3.2 **FARM: Data Files.**

Includes records electronically created or transmitted, images and related data fields taken from the following records, but not limited to.

Supersedes NC1-88-84-3 Items 1, 2, 5, 6, 7, and 8

New Protein Consultations (NPC):
Includes records submitted by developers of new proteins intended for food use. Records provide information regarding the potential toxicity or allergenicity of the proteins, as well as related records.

Premarket Notification Consultations (PNC):
Includes materials generated during interactions between CFSAN and industry prior to or related to submission of a Food Contact Notification (FCN), as well as related records.

Food Additive Petitions (FAP):
Includes formal requests for food additive regulations received from producers under 21 CFR Part 171 to permit inclusion of additives in food products Petition includes name of additive, chemical identity of additive, composition of additive, statement of proposed use, labeling, data on effects of additive, additive detection analytical methodology and additive safety investigation reports. Also includes all internal documentation supporting regulation, rejection, or denial of petition, as well as related records.

Color Additive and Diluent Petitions:
Includes formal requests for color additive or diluent regulations received from producers under 21 CFR Part 71 to permit inclusion of color additives or diluents in foods, drugs, devices, or cosmetics Petition includes name of additive, chemical identity of additive, composition of additive, statement of proposed use, labeling, data on effects of additive, additive detection analytical methodology and additive safety investigation reports. Also includes all internal documentation supporting regulation, rejection, or denial of petition, as well as related records.

GRAS Petitions (GRP):
Includes formal requests from producers for affirmation that particular substances are Generally Recognized as Safe (GRAS) for use in food under 21 CFR 170.35. Also contains notification of FDA approval or denial, as well as supporting documentation.

GRAS Notifications (GRN):
Includes requests for GRAS exemptions from producers, as well as related records.

Food Contact Notifications (FCN):
In October 1999, notifications replaced food additive petitions as formal premarket requests for the use of food contact substances such as packaging material. Notifications become effective 120 days after FDA receipt of FCN unless FDA objects to FCN. Records include notifications and FDA responses, as well as other related records.

Biotechnology Notification Files (BNF):
Includes materials collected in consultation with industry to identify and discuss relevant safety, nutritional or other regulatory issues regarding genetically modified foods. Also includes summaries of scientific and regulatory assessments of bio-engineered food, as well as agency responses to requests

Threshold of Regulation Letter (TOR):
Includes requests submitted by industry in accordance with 21 CFR 170.39 for exemption from food additive regulations.

Food Additive Master File (FMF):
Includes supporting materials from producers of food additives which may contain one or more additives Includes safety and efficacy test results, protocols, and correspondence among producers, third parties, and FDA. May include advisory opinions, data reports, and evaluation results.

Color Additive and Diluent Master File (CMF):
Includes supporting materials from producers of color additives and diluents, which may contain one or more color additives or diluents. Includes safety and efficacy test results, protocols, and correspondence among producers, third parties, and FDA

Disposition: TEMPORARY.
Cutoff at the end of the calendar year after final action is completed or product is withdrawn from the market, whichever is later. Delete/destroy when no longer needed for business or regulatory purposes, or 30 years after cutoff, whichever is latest.

~~1.3.3~~ **~~FARM: Outputs.~~** **GRS 20, item 16**
~~Includes periodic and ad hoc reports generated to support safety decisions and manage assignments~~

~~For data extracted to be loaded into FOIA or other systems, apply disposition authorized under the appropriate records series~~

~~Disposition: TEMPORARY.~~
~~Delete/destroy when no longer needed for administrative or reference purposes, whichever is later~~

~~1.3.4~~	~~**System Documentation.**~~ ~~Includes system operation and user manuals, as well as other system related materials~~ ~~**Disposition: TEMPORARY.**~~ ~~Delete/destroy when superseded or obsolete, or upon authorized deletion of the system, whichever is latest.~~	**GRS 20, Item 11a1**
~~1.3.6~~	~~**Backups.**~~ ~~Files backed up periodically to be retained in case the master file is damaged or inadvertently erased~~ ~~**Disposition: TEMPORARY.**~~ ~~Delete/destroy when the identical records have been deleted/destroyed or replaced by a subsequent backup file.~~	**GRS 20 Item 8b**
1.4	**Priority-based Assessment of Food Additive (PAFA).** PAFA is a database that maintains information on the administrative, chemical, and toxicological effects of Generally Recognized as Safe (GRAS) ingredients, as well as food and color additives approved by FDA.	**New**
1.4.1	**Food Additive Safety Profiles** Includes administrative, chemical and toxicological documentation from surveys, reports and literature on GRAS ingredients, regulated food additives and color additives used in foods. Certain information from these files is used to populate the PAFA database. **Disposition: TEMPORARY** Delete/destroy when no longer needed for administrative or reference purposes, whichever is later. Records may not be destroyed before 3 years of age.	
1.4.2	**PAFA: Data files.** Includes PAFA document type (e.g., ASP, IDR, EAF etc ,) PAFA document number, Substance name, Chemical Abstract Service Registry Number (CAS RN)or other unique identifying number, as well as other related administrative, chemistry and toxicology data supporting the safety of food ingredients. Information is gathered on chemicals in the database from surveys, reports, and literature This information forms a data-type called the Food Additive Safety Profile (ASP) record. **Disposition: PERMANENT** Transfer a snapshot of the data to the National Archives at the end of each calendar year.	
~~1.4.3~~	~~**PAFA: Outputs – Periodic Reports Available on the Internet**~~ ~~Includes data extracts accessible on the internet. The "Everything Added to Food in the United States" (EAFUS) report lists food and~~	

~~color additive, GRAS and prior sanctioned substances used in food. The "Indirect Additives" report lists food contact substances used in food packaging and equipment.~~

~~**Disposition:** Dispose of in accordance to the disposition schedule for the Web Content Management System~~

~~1.4.4~~	~~**PAFA: Outputs**~~ ~~Ad-hoc reports generated to support safety decisions.~~ ~~**Disposition: TEMPORARY.**~~ ~~Delete/destroy when no longer needed for administrative or reference purposes, whichever is later~~	**GRS 20, Items 12 and 16**
~~1.4.5~~	~~**System Documentation.**~~ ~~Includes system operations and user manuals, as well as other system related materials.~~ ~~**Disposition: TEMPORARY.**~~ ~~Delete/destroy when superseded or obsolete, or upon authorized deletion of the system, whichever is latest.~~	**GRS 20 Item 11a1**
~~1.4.6~~	~~**Backups.**~~ ~~Files backed up periodically to be retained in case the master file is damaged or inadvertently erased~~ ~~**Disposition: TEMPORARY.**~~ ~~Delete/destroy when the identical records have been deleted/destroyed or replaced by a subsequent backup file~~	**GRS 20 Item 8b**
1.5	**Import Milk Act File.** Includes reports submitted by foreign governments, such as Report on Tuberculin Tests of Cattle (FDA Form 1994), Report of Physical Examination of Cows (FDA Form 1995), Dairy Farm Sanitation Report (FDA Form 1996), and Score Card for Sanitary Inspection of Milk Plants (FDA Form 1997); milk import permits; and milk import reviews, as well as related correspondence, as required by the Federal Import Milk Act. **Disposition: TEMPORARY.** Cutoff at the end of the calendar year after expiration of milk import permit. Delete/destroy 30 years after cutoff	**Supersedes NC1-88-78-1 F-14**
1.6	**Infant Formula Files.**	**New**
1.6.1	**Infant Formula Company and Subject Files.** Includes correspondence concerning infant formula, informational materials about or submitted by infant formula companies, pre-notification information (other than notifications themselves), and notes on FDA reviews and/or actions, as well as related records Also includes foreign government policies/regulations, guidelines,	

expert group opinions, results of analytical studies on infant formula, significant scientific information on current issues, records of opinions/statements made by the Infant Formula Team, and incoming and outgoing correspondence on issues not related to notifications, as well as other related materials.

Disposition: TEMPORARY.
Cutoff at the end of the calendar year after company goes out of business. Delete/destroy after 50 years, or when no longer needed for business or regulatory purposes, whichever is latest.

1.6.2 **Premarket Notifications.**
Includes original and review copies of notifications submitted to FDA under the Infant Formula Act by infant formula manufacturers. Also includes supplemental submissions, clinical trial data, labels, processing/stability data, FDA review comments, FDA final decision documents, and correspondence, as well as related records Covers records from the late 1970s to present. 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.

1.6.2.1 **Original record copies.**

Disposition: TEMPORARY.
Cutoff at the end of the calendar year when related infant formula brand is no longer produced. Delete/destroy 50 years after cutoff, or when no longer needed for legal, research or regulatory purposes, whichever is latest

1.6.2.2 **Review Copies.**

Disposition: TEMPORARY.
Delete/destroy after final action on notification.

1.6.3 **Infant Formula Tracking System.**
Tracks notification review activities and actions by various data fields.

1.6.3.1 **Infant Formula Tracking System: Data Files.**
Includes infant formula name, infant formula number, date of submission, due date, final memo, ingredients, formula type, and review comments, as well as other related data and supporting information. Data taken from data entry forms and notifications, as well as from information directly entered into the tracking database. 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.
Cutoff at the end of the calendar year after related formula brand is no longer produced. Delete/destroy when no longer needed for business or regulatory purposes, or 50 years after cutoff, whichever is latest.

~~1.6.3.2~~ ~~**Infant Formula Tracking System: Outputs.**~~ **GRS 20, Items 16**
~~Includes reports generated in response to ad hoc queries by FDA personnel. Reports include information extracted from the tracking database by one or more data fields. 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.~~

~~For output records filed as part of other record series, apply disposition authorized for that series.~~

~~**Disposition: TEMPORARY.**~~
~~Delete/destroy when no longer needed for administrative or reference purposes, whichever is later.~~

~~1.6.3.3~~ ~~**System Documentation.**~~ **GRS 20 Item 11a1**
~~Includes system operations and user manuals, as well as other system related materials.~~

~~**Disposition: TEMPORARY.**~~
~~Delete/destroy when superseded or obsolete, or upon authorized deletion of the system, whichever is latest.~~

~~1.6.3.4~~ ~~**Backups.**~~ **GRS 20 Item 8b**
~~Files backed up periodically to be retained in case the master file is damaged or inadvertently erased.~~

~~**Disposition: TEMPORARY.**~~
~~Delete/destroy when the identical records have been deleted/destroyed or replaced by a subsequent backup file.~~

2 **Seafood Hazard Analysis and Critical Control Point (HACCP) System.** Includes data and reports that support post market food safety through inspection, analysis and control of biological, chemical and physical hazards from production to product consumption, as required by 21 CFR Part 123 or FDA guidance documents. 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.

~~2.1~~	~~**Seafood HACCP: Input Records.**~~ ~~Includes survey forms such as the Seafood HACCP Report (FDA Form 3501) and the Imported Seafood HACCP Report (FDA Form 3502) transmitted as imaged records via fax or electronically entered. Also includes data extracted from the Field Accomplishment Compliance Tracking System (FACTS) or its successor system maintained by ORA.~~ ~~**Disposition: TEMPORARY.**~~ ~~Delete/destroy when no longer needed for administrative or regulatory purposes, whichever is later.~~	**GRS 20, item 2a4, 2b or 2c**
2.2	**Seafood HACCP: Data Files.** Includes FDA establishment identifier number (FEI), firm name, firm address, inspector's name, date of inspection, date of submission, and State agency code, as well as other related data and supporting information from survey forms. **Disposition: TEMPORARY.** Cutoff at the end of the calendar year in which submitted. Delete/destroy when no longer needed for business or regulatory purposes, or 20 years after cutoff, whichever is latest.	
2.3	**HACCP: Outputs—Biennial Domestic Seafood Reports** Includes Biennial Domestic Seafood Reports updated every 2 years and posted on the FDA website. Also includes background information used to produce biennial reports. **Disposition: TEMPORARY.** Cutoff at the end of the calendar year when superseded. Delete/destroy 3 years after cutoff or when no longer needed for administrative or reference purposes, whichever is later.	
~~2.4~~	~~**HACCP: Outputs**~~ ~~Ad-hoc reports generated as needed.~~ ~~**Disposition: TEMPORARY.**~~ ~~Delete/destroy when no longer needed for administrative or reference purposes, whichever is later.~~	**GRS 20, Item 12 or 16**
~~2.5~~	~~**System Documentation.**~~ ~~Includes system operations and user manuals, as well as other system related materials.~~ ~~**Disposition: TEMPORARY.**~~ ~~Delete/destroy when superseded or obsolete, or upon authorized deletion of the system, whichever is latest.~~	**GRS 20 Item 11a1**
~~2.6~~	~~**Backups.**~~ ~~Files backed up periodically to be retained in case the master file is damaged or inadvertently erased~~	**GRS 20 Item 8b**

	Disposition: TEMPORARY. Delete/destroy when the identical records have been deleted/destroyed or replaced by a subsequent backup file.	
3	**E-mail and Word Processing System Copies.** Includes electronic copies of records created on electronic mail and word processing systems and used solely to generate a recordkeeping copy of records covered by other items in this schedule. Also includes electronic copies of records created on electronic mail and word processing systems and maintained for updating, revision, or dissemination	**New**
3.1	**Copies that have no further administrative value after creation of the recordkeeping copy.** Includes copies maintained by individuals in personal files, personal electronic mail directories, and other personal directories when used only to produce record-keeping copies. **Disposition: TEMPORARY.** Delete/destroy 180 days after the recordkeeping copy has been produced or when it has no further archival value, whichever is later	**GRS 20, Items 13 and 14**
3.2	**Copies maintained in addition to recordkeeping copies and used for dissemination, revision, or updating.** **Disposition: TEMPORARY.** Delete/destroy when dissemination, revision, or updating is completed.	**Non-record**