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: N1-088-09-6
DATE RECEIVED: 2/24/09

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~~ 196-3802

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request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10.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
3/30/09	[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 11 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	Elaine Parkey	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 GRS OR SUPERSEDED JOB CITATION	10.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 2 (see attached) Seung Ja Sinatra - FDA Records Officer — Date: 3/21/06 Ann Wion - FDA Deputy Chief Counsel — Date: 2/4/09		

CFSAN Program Records (Group 2)

File Code: Prefix = CFSAN

Item No.	File Code	Records Description and Authorized Disposition	NARA Approved Citation
1.		**75-Day Premarket Notification for New Dietary Ingredient.** As required under the Dietary Supplements and Health Education Act (section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act), notification submissions include information used by distributors and manufacturers to conclude that dietary supplements containing new dietary ingredients (NDI) would reasonably be expected to be safe when used pursuant to the conditions recommended or suggested in the labeling. Includes copies of notifications, reprints of articles from scientific literature, research information and data, information on manufacturing and controls, data and results of completed animal and/or human studies, history of use information, FDA responses, final review memos, meeting minutes, and correspondence including emails, as well as other essential background materials. Records cover from 1994 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. For original notifications, their redacted versions and copies of signed FDA responses maintained in Dockets, apply disposition authorized under Dockets records schedules. **Disposition: TEMPORARY.** Cutoff at end of the calendar year after final action is taken or product is withdrawn from the market, whichever is later. Delete/destroy when no longer needed for operational, research, or reference purposes, or 30 years after cutoff, whichever is latest.	**New**
1.1		**NDI Notification Review Tracking System.** Includes data such as, notification receipt date, review due date, review status, reviewers comments, dosage, trade and ingredient name useful in tracking the status of 75-day notification during the NDI review process. **Disposition: TEMPORARY.** Cutoff at the end of the calendar year in which final action. Delete/destroy 30 years after cutoff, which ever is latest.	
2.		**Food Standards Files.** Includes supporting documents, working files, studies, reports, copies of regulations, and reference materials relating to the development of	**Supersedes NC1-88-84-3, Item 4**

and amendment to food standards of identity, quality, and container fill, as well as documents relating to issuance of temporary marketing permits. Records cover from 1919 to present.

For official rulemaking documents such as formal petitions proposing to establish or amend standards of identity, quality or container fill; label petitions; formal FDA reviews; and final actions, as well as supporting materials maintained in Dockets, apply disposition authorized under Dockets schedules.

Disposition: TEMPORARY.
Cutoff at the end of the calendar year after enabling regulation is revoked. Delete/destroy 30 years after cutoff or when no longer needed for administrative, operational or reference purposes whichever is latest.

3. **Structure Function Claims Postmarket Notifications.** **New**
Also called 30-Day Notifications. Includes original notification letters sent under the Dietary Supplements Health and Education Act of 1994 (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act) by manufactures, packers, and distributors of dietary supplements within 30 days after the first marketing of their products; FDA letters of objection; FDA responses; FDA comments; and FDA clearance records, as well as other related materials. Records cover from 1994 to present.

For copies maintained in Dockets, apply disposition authorized under Dockets schedules.

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

4. **Color Additive Certification.**
Includes records of chemical and physical analyses of color additive samples submitted for certification,; requests for certification of color additives used in foods, drugs, medical devices and cosmetics; and FDA responses, as well as related records, in accordance with 21 CFR Parts 70 and 73. Records cover from 1938 to present.

4.1 **Certification Requests, Certificates, and FDA Responses (Record Copies).** **Supersedes NC1-88-78-1, item F-9**
Includes requests for certification, certificates, FDA rejections, review reports, and analytical results, as well as related records. 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 final action is completed. Delete/destroy when no longer needed for legal, research or regulatory purposes, or 30 years after cutoff, whichever is latest.

~~4.2~~ ~~**Copies used to produce record copies.**~~ **GRS 20, Item 2a4**
~~Includes paper copies described in 3310 used for imaging to create record copies.~~

~~**Disposition: TEMPORARY.**~~
~~Delete/destroy after records are successfully scanned or copied on electronic storage media and data fields have been entered into the Color Certification System (COLORS) and verified for accuracy, or when records are no longer needed to reconstruct or serve as backup to the master file, whichever is later.~~

~~4.3~~ ~~**Backups.**~~ **GRS 20**
~~Files backed up periodically to be retained in case the master file is damaged or inadvertently erased.~~ **Item 8b**

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

4.4 ~~**Color Additive Samples.**~~ **Non-record**

~~**Disposition: TEMPORARY.**~~ **Withdrawn**
~~Cutoff at date of submission. Delete/destroy 3 years after cutoff, or when no longer needed for reference purposes, whichever is later.~~ **6/16/09**

4.5 **Color Certification System (COLORS).**
Facilitates electronic submission of requests for color additive certifications and tracks certification processes. Also maintains results of laboratory analysis performed for color samples and generates batch certification of certifiable color additives added to foods, drugs, cosmetics, and medical devices. 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.

4.5.1 **COLORS: Data Files.**
Includes company data, sample and analytical data submitted by companies, FDA laboratory results, reviewer comments and certification status, as well as other related data and supporting information.

Disposition: **TEMPORARY.**
Cutoff at the end of the calendar year when color additive no longer available on the market or certification has been rescinded, whichever is later. Delete/destroy when no longer needed for business or

regulatory purposes, or 30 years after cutoff, whichever is latest.

~~4.5.2~~	~~**COLORS: Outputs.**~~ ~~Includes status and ad hoc reports produced as needed.~~ ~~For data extracted to produce/print official certificates, apply disposition authorized under File Code 3310.~~ ~~**Disposition: TEMPORARY.**~~ ~~Delete/destroy when no longer needed for administrative or reference purposes, whichever is later.~~	**GRS 20, items 5 & 16**
~~4.5.3~~	~~**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**
~~4.5.4~~	~~**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**
5	**Pasteurized Milk Ordinance (PMO), Grade "A" Milk Program.**	**New**
5.1	**Historic Ordinances Files.** Includes original documentation of the Grade "A" Milk Safety Program and subsequent revisions related to the Grade "A" Pasteurized Milk Ordinance (PMO), the Grade "A" Dry Milk Ordinance (DMO), the Evaluation of Milk Laboratories (EML), the Standards for the Fabrication of Single-Service Containers and Closures for Milk and Milk Products (SSCC), the Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments (NCIMS), and the Methods of Making Sanitation Ratings of Milk Shippers (MMSR). Records cover from 1934 to present. **Disposition: TEMPORARY.** Cut off at the end of the calendar year in which revision occurs. Delete/destroy 30 years after cutoff or when no longer needed for regulatory, administrative or reference purposes, whichever is latest.	
5.2	**Coded Memoranda.** Includes guidance documents issued by FDA on procedures, policies and methodologies related to the Grade "A" Milk Safety Program. Records include Memoranda of Interpretation (M-a), Memoranda of	**Supersedes NC1-88-78-1 F15**

Information (M-I), Memoranda of Milk Ordinance Equipment Compliance (M-b), and Memoranda of Conference Actions (IMS-a). Records cover 1938 to present.

Disposition: TEMPORARY.
Cutoff at the end of the calendar year in which new or revised memoranda occurs. Delete/destroy 30 years after cutoff or when no longer needed for regulatory, administrative or reference purposes, whichever is latest.

5.3 **State Program Evaluation Files.**
Includes triennial evaluation records of State Grade "A" Milk Safety Programs generated by the FDA Certified Regional Milk Specialists, as well as review comments by the CFSAN Milk Safety Team (MST).

5.3.1 **Records with CFSAN review notes maintained in program office record keeping systems.**

Disposition: TEMPORARY.
Cutoff at end of the fiscal year in which evaluation occurs. Transfer to FRC 6 years after cutoff. Delete/destroy 10 years after cutoff.

5.3.2 **Records maintained in FDA field offices.**

Disposition: TEMPORARY.
Cutoff at end of the fiscal year in which evaluation occurs. Transfer to FRC 6 years after cutoff. Delete/destroy 10 years after cutoff.

5.4 **Regional Milk Specialists Certification Records.**
Includes documentation on the certification process, as well as certification and certification renewal paperwork related to FDA Certified Regional Milk Specialists.

Disposition: TEMPORARY.
Cutoff when superseded or obsolete, whichever is later.
Delete/destroy 6 years after cutoff.

5.5 **Interstate Milk Shippers (IMS) Listing System.**
IMS facilitates electronic submission of the Interstate Milk Shippers Report and Single Service Certification forms by State Rating Officers or Consultants. It allows FDA to electronically process review activities and to publish the IMS List. Includes FDA certified State Rating Officers' evaluations of sanitation compliance with the PMO for dairy farms and plants, as well as related documents.

~~5.5.1~~ ~~**IMS Reports, Certification, and Check Ratings: Input Records.**~~ **GRS 20, Item 2a4**
~~Includes data from the Interstate Milk Shippers Report (FDA Form 2359i), the Report of Single Service Certification (FDA Form 2359d), Interstate Milk Shipper Check Rating Report (FDA Form 2359h), rating score of IMS Listing, audit of Single Service Container Manufacture and copies of State letters requesting removal of shippers~~

~~from the IMS list, as well as data from the FDA Regional Milk Specialists' check rating (auditing) evaluation of compliance with the PMO for dairy farms, milk plants, and Single-Service Container manufacturers, and related supporting materials.~~

~~**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 backup to, the electronic records.~~

5.5.2 **IMS: Data Files.**
Includes shipper's name, shipper's address, plant code, product codes, sanitation compliance, enforcement rating scores, rating agency, and rating date, as well as other related data and supporting documentation.

Disposition: TEMPORARY.
Cutoff at the end of the calendar year when company is no longer in business or certification expires or is rescinded, whichever is later. Delete/destroy when no longer needed for business or regulatory purposes, or 4 years after cutoff, whichever is latest.

5.5.3 **IMS: Outputs.**
Includes online list of certified Interstate Milk Shippers.

Disposition: TEMPORARY.
Cutoff at the end of the calendar year when superseded by new data. Delete/destroy when no longer needed for business or regulatory purposes, or 4 years after cutoff whichever is later.

~~5.5.4~~ ~~**System Documentation.**~~ **GRS 20**
~~Includes system operations and user manuals, as well as other system related materials~~ **Item 11a1**

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

~~5.5.5~~ ~~**Backups.**~~ **GRS 20**
~~Files backed up periodically to be retained in case the master file is damaged or inadvertently erased.~~ **Item 8b**

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

6 **Food Label and Package Survey (FLAPS) Records.**
Includes records documenting evaluation of food labels, as well as market survey data monitoring manufacturers' compliance with food labeling regulations and guidance; supporting food safety, regulatory

and policy decisions; and conducting economic impact analysis. Records cover from the late 1970s to present.

6.1	**Food Labels and Market Survey Data (Record copies).** Data taken from and image files of food labels collected from processed/packaged products, including market survey data of food and dietary supplement products sold in US supermarkets, drug stores and mass merchandisers. Data includes brand name, items sold within brand, company name, amount sold in units, dollar sales by category, price, and product descriptors, as well as other market related information. **Disposition: TEMPORARY.** Cutoff at the end of the calendar year after completion of analysis. Delete/destroy 15 years after cutoff, or when no longer needed for legal, research or regulatory purposes, whichever is latest.	**Supersedes NC1-88-82-4 Item F-71b**
~~6.2~~	~~**Copies used for scanning and data collection forms.**~~ ~~Includes original food labels used for scanning, as well as data collection forms containing information taken from food labels.~~ ~~**Disposition: TEMPORARY.**~~ ~~Delete/destroy after food labels are scanned, label data are successfully entered into an automated analytical tool and records are verified for accuracy.~~	**GRS 20, Item 2a4**
6.3	**FLAPS final reports.** Includes final reports analyzing the relationship between data on food labels and market data, as well as essential supporting materials. **Disposition: TEMPORARY.** Cutoff at the end of the calendar year in which published. Delete/destroy 15 years after cutoff, or when no longer needed for research or reference purposes.	
7	**Voluntary Cosmetic Registration Program (VCRP).** Post market reporting system used by manufacturers, packers, and distributors of cosmetic products in commercial distribution in the U.S. In accordance with 21 CFR Parts 710 and 720, manufacturers, packers, and distributors voluntarily register their establishments and file product ingredient statements in order to participate in VCRP and to receive information about cosmetic ingredients.	
~~7.1~~	~~**VCRP Database.**~~ ~~The system accepts the registration of cosmetic product establishments and the filing of cosmetic product formulations, amendments, and/or discontinuances of previously filed formulations.~~	
~~7.1.1~~	~~**VCRP: Input Records.**~~ ~~Includes FDA Forms (Form 2511, Registration of Cosmetic Product Establishment; Forms 2512 and 2512a, Cosmetic Product Ingredient~~	**GRS 20, item 2a4**

Statement; and Form 2514, Notice of Discontinuance of Commercial Distribution of Cosmetic Product Formulation), as well as supporting materials submitted by industry. Records cover from 1973 to present. Records may be input manually into the system or scanned.

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 backup to, the electronic records, whichever is later.

7.1.2	**VCRP: Data Files.** Includes company name, product identification, product name, and ingredients, as well as other related data and supporting information. **Disposition:** **TEMPORARY.** Cutoff at the end of the calendar year when company is no longer in business or product is no longer in commercial distribution, whichever is later. Delete/destroy when no longer needed for business or regulatory purposes, or 30 years after cutoff, whichever is latest.	**Supersedes NC1-88-79-2, Item F69; NC1-88-83-1, Items F73a, F73b and F73c** **Item previously approved under N1-088-07-2, item 6.2.2**
7.1.3	**VCRP: Output Records.** Includes ad hoc reports generated to respond to inquiries by industry, as well as other ad hoc reports produced as needed. **Disposition:** **TEMPORARY.** Delete/destroy when no longer needed for administrative or reference purposes, whichever is later.	**GRS 20, Item 16**
7.1.4	**System Documentation.** Includes system operations and user manuals, as well as other systems related materials. **Disposition:** **TEMPORARY.** Delete/destroy when superseded or obsolete, or upon authorized deletion of the system, whichever is latest.	**GRS 20 Item 11a1**
7.1.5	**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**
8	**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	**GRS 20, Items 13 and 14**

~~electronic copies of records created on electronic mail and word processing systems and maintained for updating, revision, or dissemination.~~

~~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.~~

~~8.1~~ ~~**Copies maintained in addition to record-keeping copies and used for dissemination, revision, or updating.**~~ **Non-record**

~~**Disposition:** TEMPORARY.~~
~~Delete/destroy when dissemination, revision, or updating is completed.~~