The U.S. FDA's Food Contact Substance Notification Program

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U.S. Food Regulations

- Federal Food Drug and Cosmetic Act (FD&C Act)
  - Congress passed in 1938
  - Amended in 1958, includes definition of “food additive”
- 1958 Amendment:
  - Required pre-market approval of new uses of food additives
  - Established the standard of safety, the standard of review, and formal rulemaking procedures for food additives
- Generally Recognized as Safe (GRAS) Substances:
  - Are excepted from the definition of a food additive
- Delaney Clause

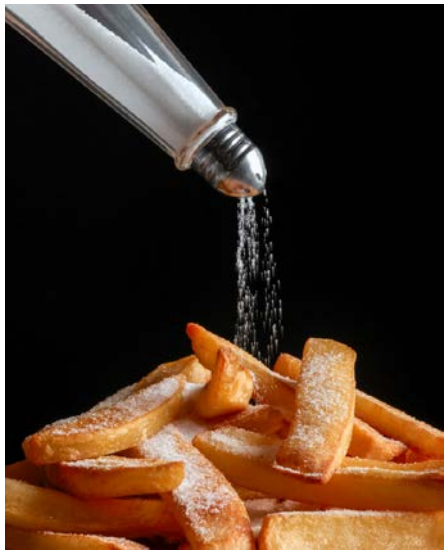
Delaney Clause

"Provided, That no [food] additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal."

21 U.S.C. 348(c)(3)(A)

Food Additive

- The term “food additive” means:
  - “any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food.” *FD&C Act §201(s)*



General Provisions of Food Additives

- General Provisions of Food Additives and Definitions: Title 21 of the Code of Federal Regulations (21 CFR) Part 173.3

- Safety Standard:
  - "Safe or safety means that there is a reasonable certainty in the minds of competent scientists that **the substance is not harmful under the conditions of its intended use**." 21 CFR 170.3(i)

Food Contact Notification Program

- The Food and Drug Administration Modernization Act (FDAMA) – amended the FD&C Act in 1997
  - Defined “food contact substance”
  - Established the food contact substance notification (FCN) program for authorizing new uses of food contact substances
    - Same safety standard as direct food additives
    - If FDA concludes there is a reasonable certainty of no harm from the intended use of the food contact substance, we allow the FCN to become effective. If not, we object to it.

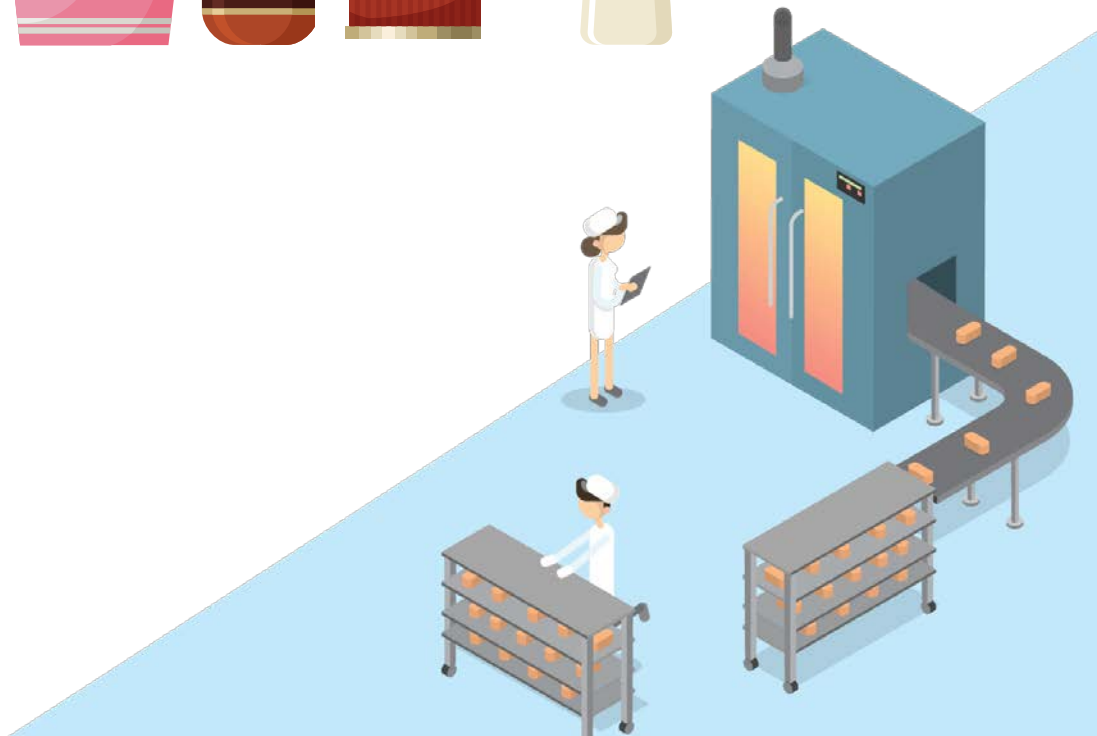
Food Contact Substance

- Food Contact Substance (FCS) means “any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have a technical effect in such food.” *FD&C Act §409(h)(6)*

Food Contact Materials

Food Packaging
Polymers
Can coatings
Paper coatings
Adhesives

Food Processing
Filters
Lubricants
Conveyor belts
Antimicrobial agents



Food Contact Substance

- Food Contact Materials are composed of food contact substances
- FDA reviews individual substances not the food contact material
- Examples of Food Contact Substances:
  - Coatings
  - Polymers
  - Paper/Paperboard Products
  - Adhesives
  - Stabilizers/Antioxidants
  - Ingredients in packaging
    - Colorants, antioxidants, antimicrobials, etc.
  - Secondary Direct Additives
    - Ion exchange resins, boiler water additives, etc.

Regulatory Pathways for Food Additives

Comparison of Mechanisms for Food Additives: Food Additive Petition, FCN, Threshold of Regulation Exemption (TOR)			
	Petition	**FCN**	**TOR**
Allowed exposure	Dietary Concentration: > 1 ppm	Dietary Concentration: < 1 ppm	Dietary Concentration: < 0.5 ppb
Required Safety Data	Case-by-Case (Usually > than FCN requirement)	Specific requirements based on exposure tiers (see Guidance)	Carcinogenicity only
Are study reports provided?	Required	Required	Literature search only
Environmental Review?	Required	Required	Required
Is submission to FDA required before marketing product?	Required	Required	Required
Who can utilize result?	Any manufacturer	Only listed manufacturer/supplier	Any manufacturer

How to Determine the Regulatory Status of a FCS

- If a substance is reasonably expected to become a component of food as a result of its intended use, then the substance must be authorized for the intended use through:
  - A regulation listed in 21 CFR
  - An effective FCN (for a specific manufacturer/supplier)
  - A Threshold of Regulation (TOR) exemption
  - The substance has Generally Recognized As Safe (GRAS) status
  - A prior sanction letter

Food Contact Authorization for the Seller

- If you are selling a food contact product, it is your responsibility to ensure that your food contact material is in compliance with the applicable authorizations based on the specifications/limitations outlined in each regulation or authorizing mechanism

- Letter of guaranty
  - 21 CFR 7.13 Suggested forms of guaranty
  - The letter must be signed by the manufacturer or an agent who resides in the United States

FCS: Safe Conditions of Use

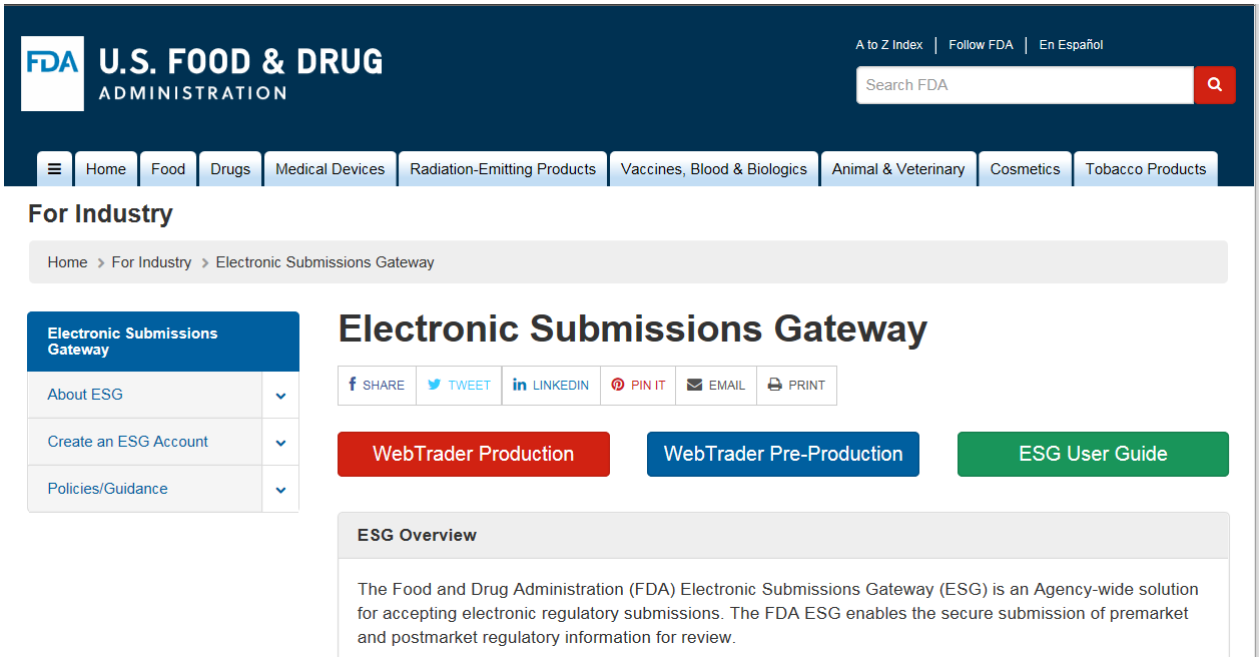
- 21 CFR 174.5
- Food additive substances may be safely used predicate usage under conditions of **good manufacturing practices**
- If a regulated food-packaging material were found on appropriate test to impart odor or taste to a specific food product, this would be considered food adulteration

When Should a FCN be Submitted

- FCNs are required for **new uses** of food contact substances (FCSs) that are **food additives**
  - Unregulated FCSs or new use for previously regulated FCSs

- FCNs are required for **new uses** of substances **not considered food additives for other uses**
  - Substances that are GRAS, Prior-Sanctioned, or Constituents of Food Additives

How to Submit a FCN



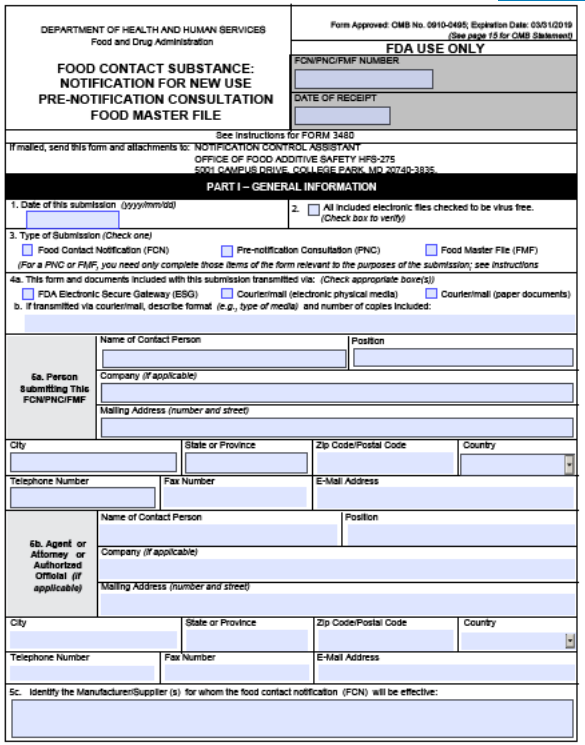
https://www.fda.gov/forindustry/electronicsubmissionsgateway/default.htm

OR

Notification Control Assistant
Office of Food Additive Safety, HFS-275
5001 Campus Drive
College Park, MD 20740

FCN Submission

- Form 3480 (FCN Application)
- Administrative
- Chemistry
- Toxicology
- Environmental
- Microbiology*



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

FOOD CONTACT SUBSTANCE: NOTIFICATION FOR NEW USE PRE-NOTIFICATION CONSULTATION FOOD MASTER FILE

Form Approved: OMB No. 0910-0495; Expiration Date: 03/31/2019 (See page 15 for OMB Statement)

FDA USE ONLY

FCN/PNC/FMF NUMBER

DATE OF RECEIPT

See Instructions for FORM 3480

If mailed, send this form and attachments to: NOTIFICATION CONTROL ASSISTANT
OFFICE OF FOOD ADDITIVE SAFETY HFS-275
5001 CAMPUS DRIVE, COLLEGE PARK, MD 20740-3835

PART I – GENERAL INFORMATION

1. Date of this submission (yyyy/mm/dd)

2. ☐ All included electronic files checked to be virus free. (Check box to verify)

3. Type of Submission (Check one)
☐ Food Contact Notification (FCN) ☐ Pre-notification Consultation (PNC) ☐ Food Master File (FMF)
(For a PNC or FMF, you need only complete those items of the form relevant to the purposes of the submission; see instructions

4a. This form and documents included with this submission transmitted via: (Check appropriate box(s))
☐ FDA Electronic Secure Gateway (ESG) ☐ Courier/mail (electronic physical media) ☐ Courier/mail (paper documents)
b. If transmitted via courier/mail, describe format (e.g., type of media) and number of copies included:

6a. Person Submitting This FCN/PNC/FMF
Name of Contact Person | Position
Company (if applicable)
Mailing Address (number and street)
City | State or Province | Zip Code/Postal Code | Country
Telephone Number | Fax Number | E-Mail Address

6b. Agent or Attorney or Authorized Official (if applicable)
Name of Contact Person | Position
Company (if applicable)
Mailing Address (number and street)
City | State or Province | Zip Code/Postal Code | Country
Telephone Number | Fax Number | E-Mail Address

5c. Identify the Manufacturer/Supplier (s) for whom the food contact notification (FCN) will be effective:

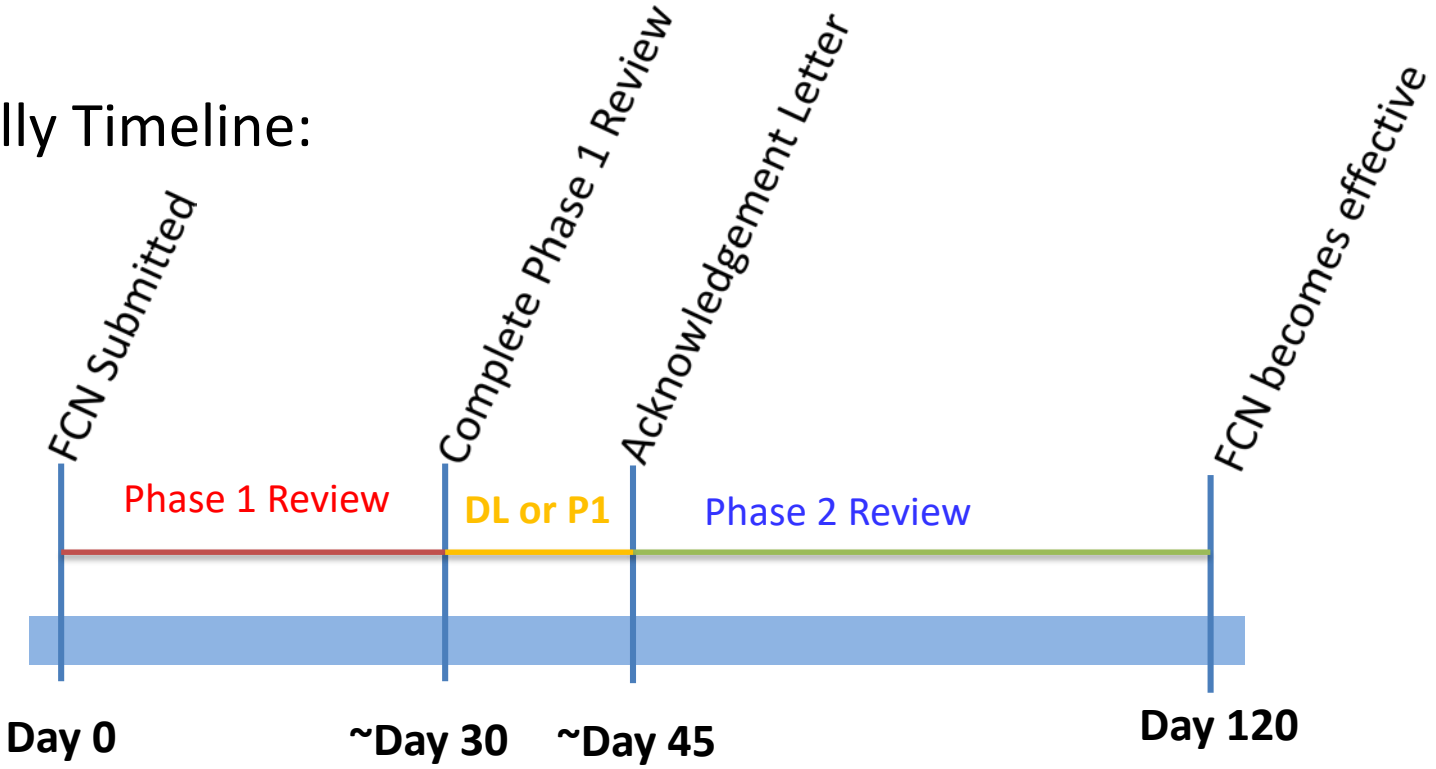
- Burden for demonstrating safety lies with the notifier

https://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/default.htm

Timeline for FCN

- Statutory 120-day review period
- If FDA does not object within the 120-days, then the FCN will automatically become effective

- Typically Timeline:



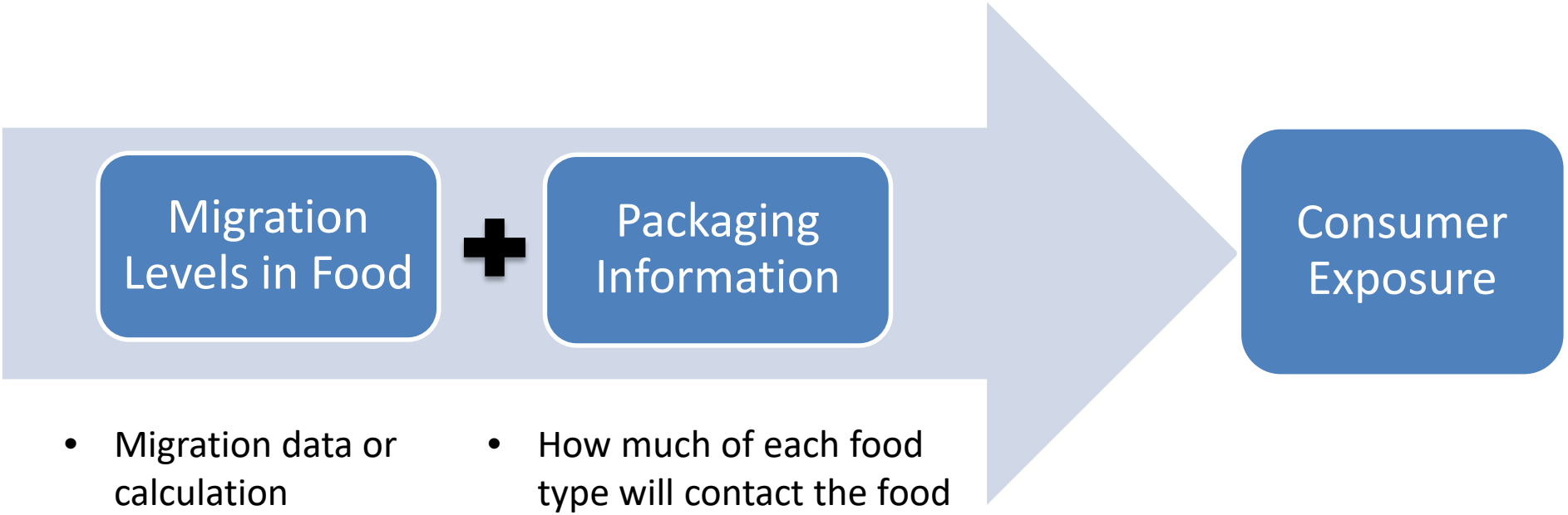
FCN Chemistry Information

- **What migrates to food?**

- Identity
  - Physical/Chemical Information
- Manufacturing Process
  - Impurities
- Conditions of Use
  - Food Types to contact
  - Temperatures the FCS will be used
- Stability
- Technical Effect
- Migration Levels of the FCS and Impurities to Food
- Exposure estimates based on migrants

Exposure Assessment

- Estimate potential **consumer exposure** to a substance including all impurities and breakdown products

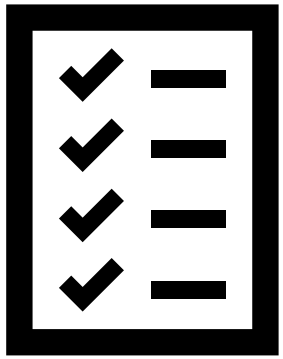


- Migration data or calculation

- How much of each food type will contact the food contact article?
- How much of the daily diet will contact the food contact article?

FCN Toxicology Information

Toxicology data needed to demonstrate safety at the level of consumer exposure to an FCS and its constituents



- **Safety Narrative (SN)**
  - Describes the scientific basis of the notifier's safety determination
- **Comprehensive Toxicology Profile (CTP)**
  - All unpublished and published safety studies and related information relevant to the safety assessment

*FDA has an **exposure-driven tiered** approach for safety testing*

FCN Environmental Information

National Environmental Protection Act (NEPA) and 21 CFR Part 25

Environmental Assessment (EA)

- A public document that stands alone
- Describes the environmental impacts from the use of the FCS, including he fate of the FCS and its constituents in the environment
- Required if use does not qualify for a CATEX or if extraordinary circumstances apply

Or…

Categorical exclusion (CATEX)

- A citation of one or more CATEX claimed
- A statement that no extraordinary circumstances exist that would require the preparation of an EA

Threshold of Regulation (TOR) Exemption

- 21 CFR 170.39
- TOR Eligibility:
  - Used in a food-contact article
  - Substance has no technical effect in or on the food to which it migrates
  - Dietary concentration $\leq$ 0.5 ppb (1.5 µg/p/d), or
    - Substance is currently regulated for direct addition to food, and exposure from the proposed use $\leq$ 1% of the ADI
  - Not shown to be a carcinogen in humans or animals, and no reason to suspect that the substance is a carcinogen
  - Substance has no significant adverse impact on the environment
- Notwithstanding these criteria, FDA reserves the right to decline to grant an exemption in those cases in which available information establishes that the proposed use may pose a public health risk

Pre-Notification Consultations

- Questions for the FDA?
  - Submit an inquiry to FDA by sending an email to: premarkt@fda.hhs.gov
- Need in depth help on a FCN submission?
  - Submit a request for a pre-notification consultations (PNC) for a pre-review of your FCN submission or guidance on a specific area of your submission
- Regulatory status questions?
  - Submit Form 3479 for FDA to review and provide our opinion on the regulatory status of a formulation or substance(s)

Summary

- All substances in food packaging where the use may reasonably be expected to become a component of food must be GRAS, prior-sanctioned, or subject to premarket authorization
  - Work with manufacturer/supplier that materials are compliant with applicable regulations for the intended use
- FCNs are necessary for any new intended use of a food additive or food contact substance, or for substitutional uses for a new manufacturer.
- FCN submissions must contain sufficient scientific information to demonstrate that the FCS subject of the notification is safe for the intended use. *21 U.S.C. 348(h)(1)*
- FDA encourages PNCs for any future FCN

Questions

premarkt@fda.hhs.gov

(240) 402-1200

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Online Resources

- Packaging & Food Contact Substances Guidance
  - https://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/default.htm
- Inventory of Effective FCNs
  - https://www.accessdata.fda.gov/scripts/fdcc/?set=fcn
- How to Determine the Regulatory Status of a Food Additive
  - https://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/ucm228269.htm
- Threshold of Regulation Exemptions
  - https://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/ThresholdRegulationExemptions/default.htm
- Inventory of Environmental Impact Decisions for FCNs
  - https://www.accessdata.fda.gov/scripts/fdcc/?set=ENV-FCN
- CEDI Database
  - https://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/CEDI/ucm2006857.htm
- Recycled Plastics in Food Packaging
  - https://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/RecycledPlastics/default.htm