U.S. FOOD & DRUG ADMINISTRATION

FDA Updates

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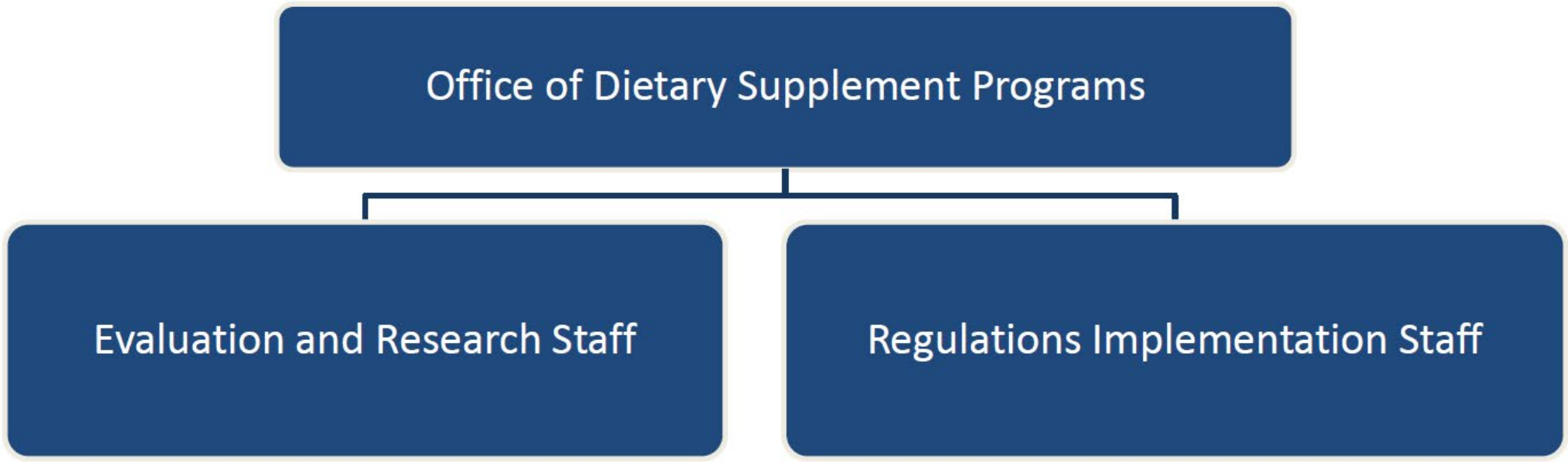
FDA/CFSAN/Office of Dietary Supplement Programs (ODSP)

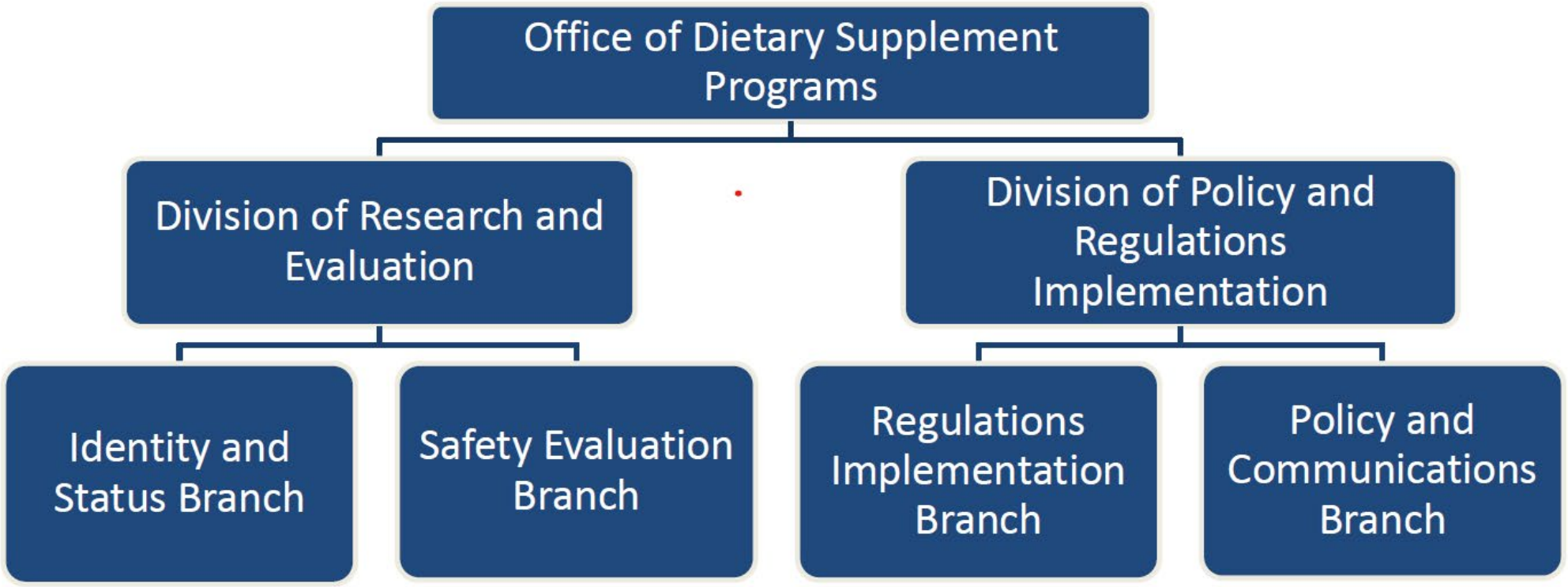
Agenda

- ODSP Update
- Guidance Update
- Education Initiatives
- ODSP Priorities

ODSP Former Structure



ODSP Current Structure



Dietary Supplement Authority

- Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et. seq.)
- Dietary Supplement Health and Education Act (DSHEA)
  - Defined the term dietary supplement
  - Established requirements for new dietary ingredient premarket review
  - CGMPs
  - Included dietary supplements under the adulteration provisions

Definition – 201(ff)(1)

Product (other than tobacco) that:

- Is intended to supplement the diet that
- Bears or contains one or more of the following dietary ingredients:
  - Vitamin,
  - Mineral,
  - Herb or other botanical,
  - Amino acid,
  - Dietary substance for use by man to supplement the diet by increasing the total dietary intake, or
  - Concentrate, metabolite, constituent, extract, or combination of any of the above ingredients

Definition – 201(ff)(2)

A dietary supplement is a product that:

(A) Is intended for ingestion,

(e.g., does not include topical products, nasal gels)

(B) Is not represented for use as a conventional food or sole item of a meal or the diet, and

(C) Is labeled as a dietary supplement.

Definition – 201(ff)(3)

- Does not include an article that:
  - Is approved as a new drug, antibiotic, or biologic, or
  - Has been authorized for investigation as a new drug, antibiotic, or biologic for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public.
  - Unless the article was "marketed" as a dietary supplement or as a food before such approval or authorization.

Distinguished from Conventional Foods

- Dietary supplements may not be:
  - Represented for use as conventional food
  - Represented as "sole item of a meal or the diet"
- Nutrition labeling
  - Conventional foods: Nutrition Facts
  - Dietary supplements: Supplement Facts

New Dietary Ingredient Notifications

- FDCA § 413(a)(2)
  - Established the requirement that manufacturers or distributors must submit a notification to FDA 75 days prior to introducing a new ingredient to market
  - Definition in FDCA § 413(d)
  - NDI notifications must meet the requirements of 21 CFR 190.6 to be considered complete
  - Not an approval

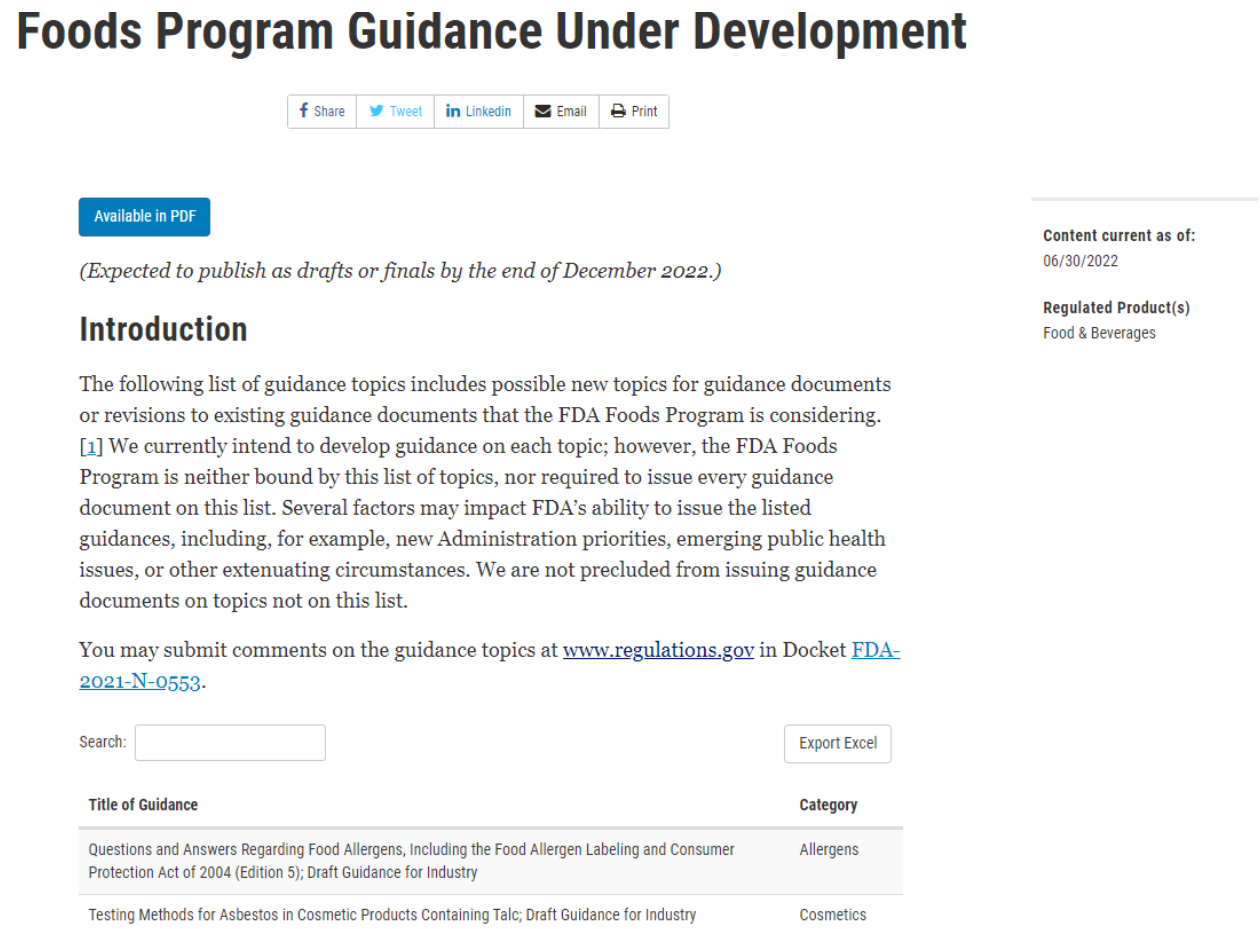
NDI Defined

- Marketed after October 15, 1994?
- Present in the food supply as an article used for food?
- Chemically altered?

	New Dietary Ingredient (NDI)	NDI notification required?
A dietary ingredient that was marketed in the U.S. before October 15, 1994	No	No
A dietary ingredient that was NOT marketed in the U.S. before October 15, 1994, AND was present in the food supply as an article used for food which has	Yes	See a) or b)
a) not been chemically altered	Yes	No
b) been chemically altered	Yes	Yes
A dietary ingredient that was NOT marketed in the U.S. before October 15, 1994, AND was NOT present in the food supply as an article used for food.	Yes	Yes

https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm257563.htm

Food Program Guidance Under Development



Foods Program Guidance Under Development

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Available in PDF

(Expected to publish as drafts or finals by the end of December 2022.)

Introduction

The following list of guidance topics includes possible new topics for guidance documents or revisions to existing guidance documents that the FDA Foods Program is considering. [1] We currently intend to develop guidance on each topic; however, the FDA Foods Program is neither bound by this list of topics, nor required to issue every guidance document on this list. Several factors may impact FDA's ability to issue the listed guidances, including, for example, new Administration priorities, emerging public health issues, or other extenuating circumstances. We are not precluded from issuing guidance documents on topics not on this list.

You may submit comments on the guidance topics at www.regulations.gov in Docket FDA-2021-N-0553.

Search:

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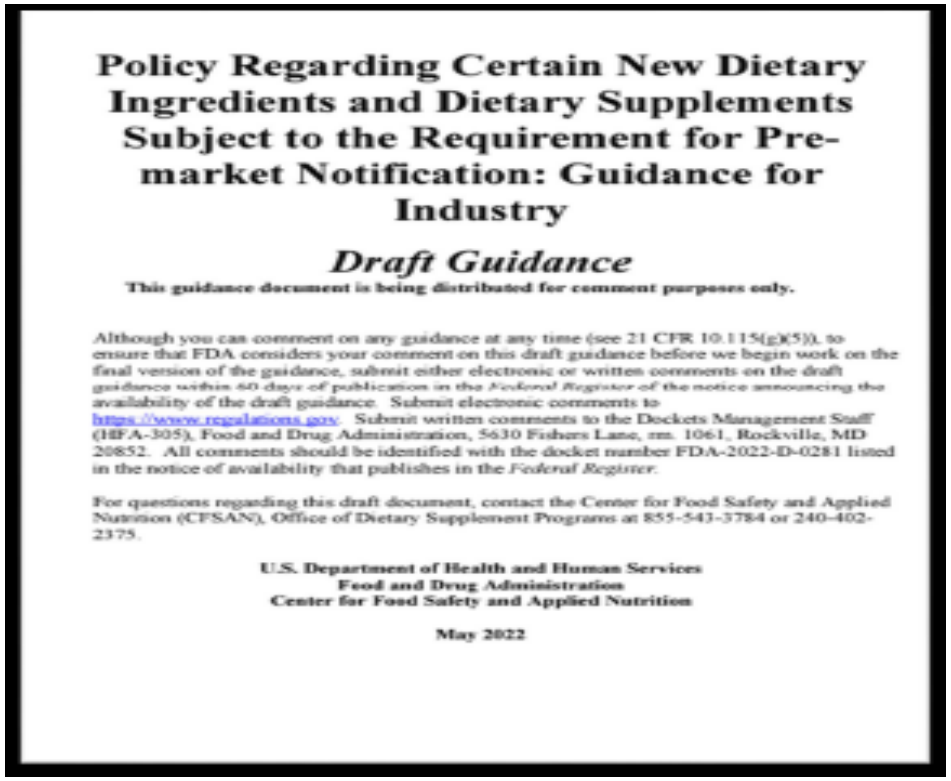
Title of Guidance	Category
Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 5); Draft Guidance for Industry	Allergens
Testing Methods for Asbestos in Cosmetic Products Containing Talc; Draft Guidance for Industry	Cosmetics

Content current as of:
06/30/2022

Regulated Product(s)
Food & Beverages

Draft Guidance

- Comment Period Closed on July 19, 2022



Policy Regarding Certain New Dietary Ingredients and Dietary Supplements Subject to the Requirement for Pre-market Notification: Guidance for Industry

Draft Guidance

This guidance document is being distributed for comment purposes only.

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on this draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2022-D-0281 listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact the Center for Food Safety and Applied Nutrition (CFSAN), Office of Dietary Supplement Programs at 855-543-3784 or 240-402-2375.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

May 2022

FDA NEWS RELEASE

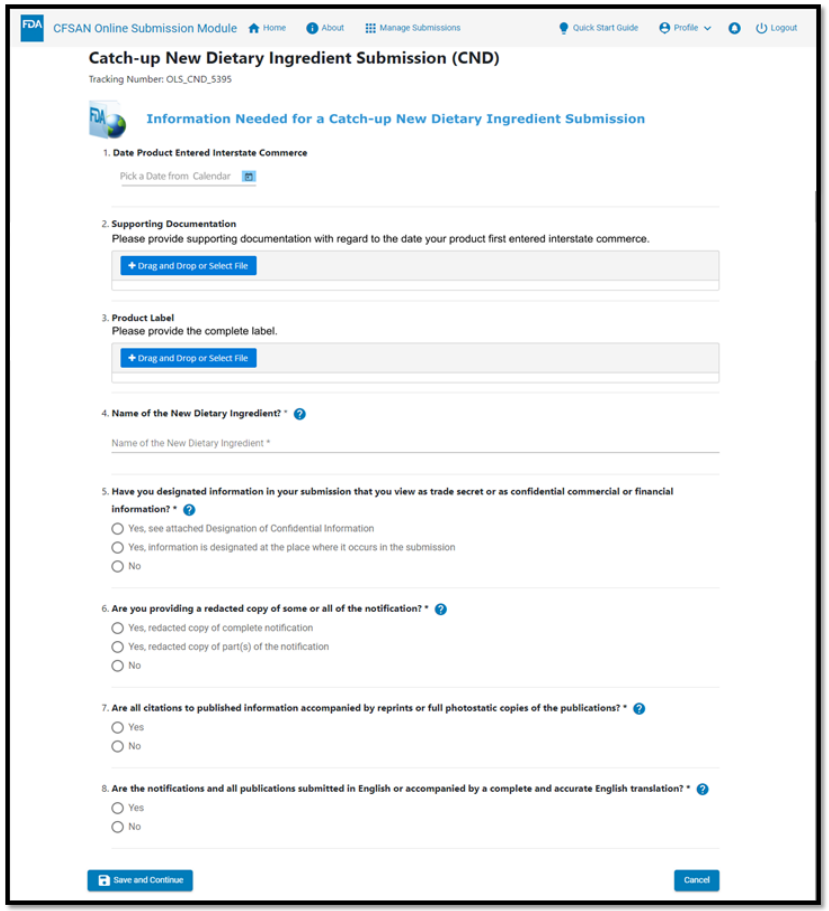
New FDA Draft Guidance Aims to Increase Safety Information About Dietary Supplement Marketplace

For Immediate Release: May 31, 2022

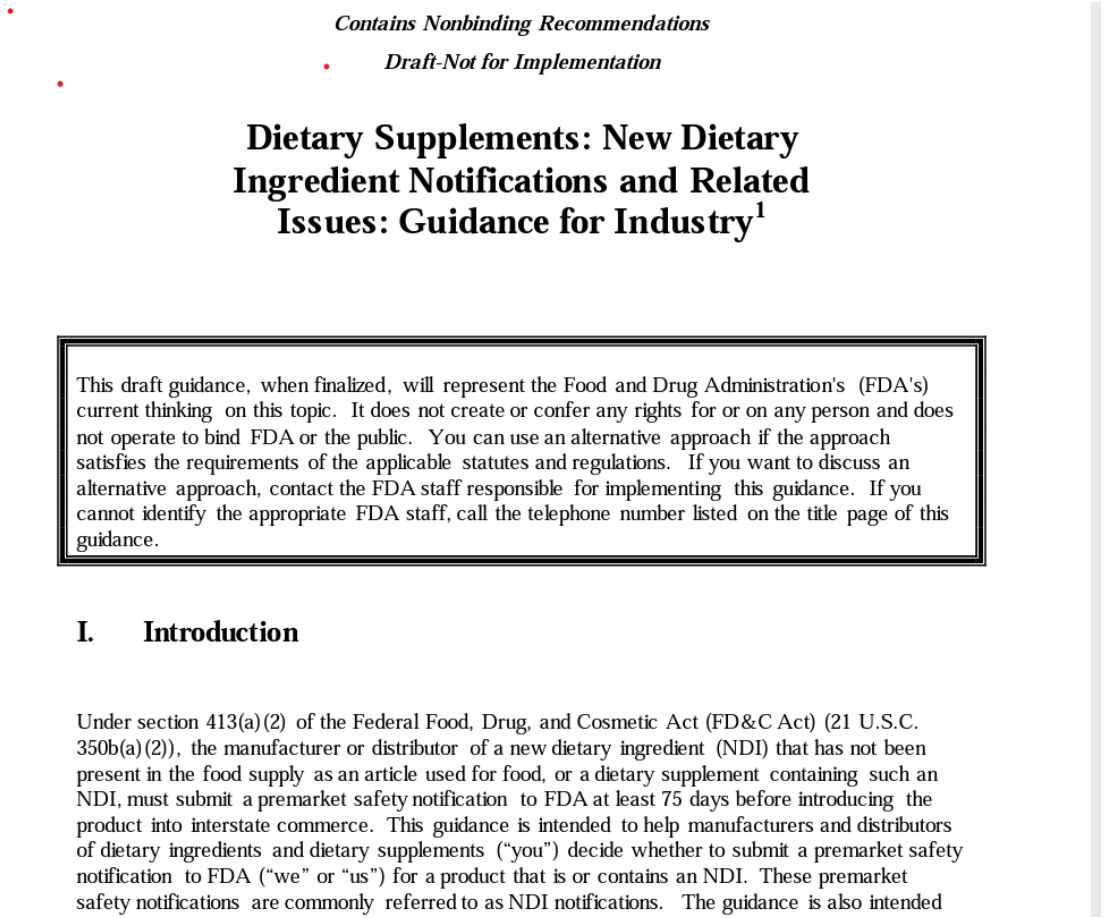
Today, the U.S. Food and Drug Administration announced the availability of a draft guidance aimed at increasing the amount of safety information the agency has about the dietary supplement marketplace by providing the industry an opportunity to submit late new dietary ingredient (NDI) notifications.

The FDA wants consumers who use dietary supplements to know that today's draft guidance, if finalized, will advise the dietary supplements industry that the agency intends to exercise enforcement discretion, for a limited time and in limited circumstances, to encourage manufacturers and distributors to correct any past failures to submit a required NDI notification. By providing industry with an opportunity to correct past failures to submit required safety information, the FDA can gain more safety information about the dietary supplement marketplace and better protect public health.

Catch-up New Dietary Ingredient Submission (CND)



More Guidance to Come



Contains Nonbinding Recommendations

Draft-Not for Implementation

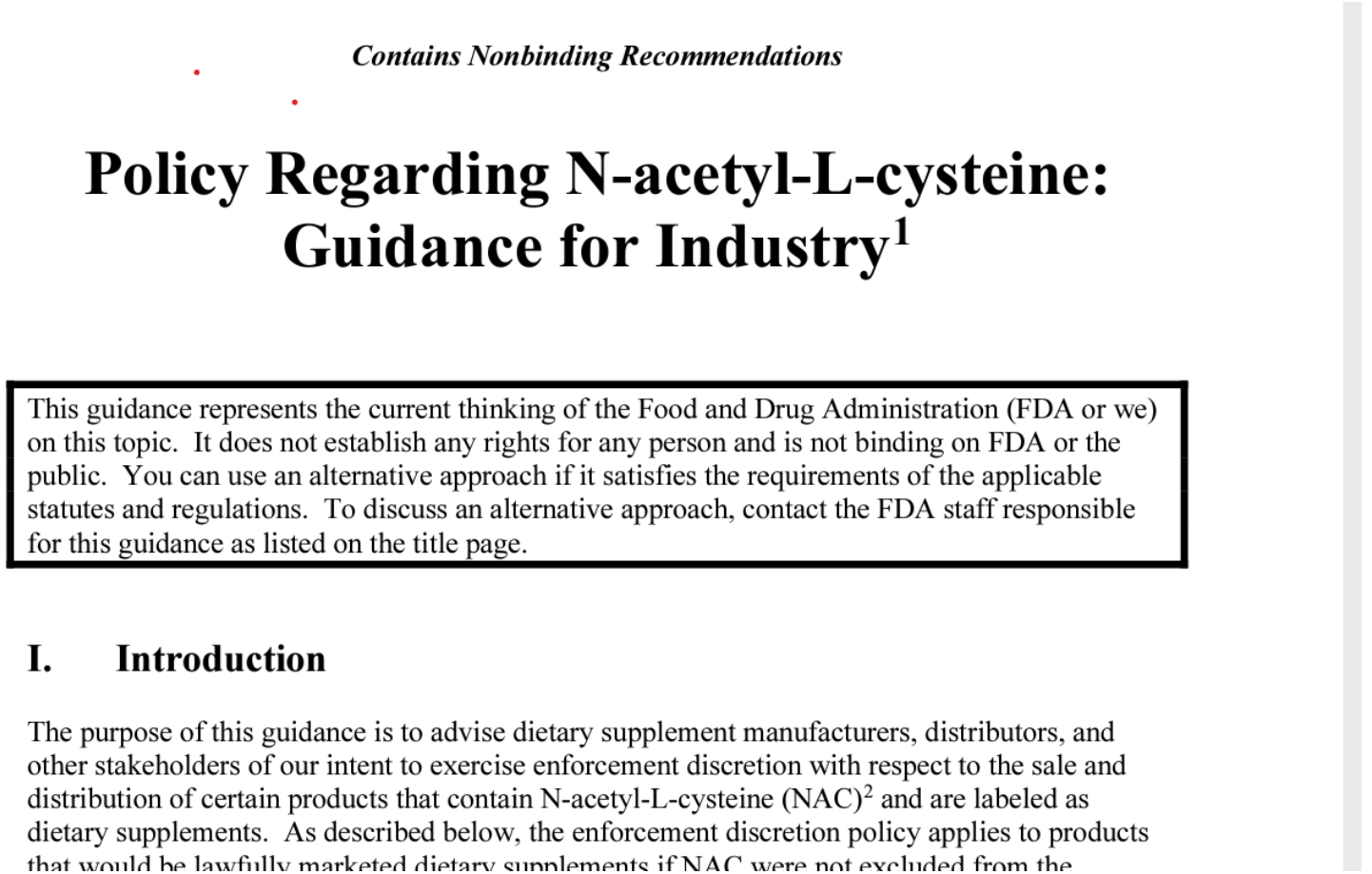
Dietary Supplements: New Dietary Ingredient Notifications and Related Issues: Guidance for Industry[1]

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

I. Introduction

Under section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350b(a)(2)), the manufacturer or distributor of a new dietary ingredient (NDI) that has not been present in the food supply as an article used for food, or a dietary supplement containing such an NDI, must submit a premarket safety notification to FDA at least 75 days before introducing the product into interstate commerce. This guidance is intended to help manufacturers and distributors of dietary ingredients and dietary supplements ("you") decide whether to submit a premarket safety notification to FDA ("we" or "us") for a product that is or contains an NDI. These premarket safety notifications are commonly referred to as NDI notifications. The guidance is also intended

Final Guidance



Contains Nonbinding Recommendations

Policy Regarding N-acetyl-L-cysteine: Guidance for Industry[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

The purpose of this guidance is to advise dietary supplement manufacturers, distributors, and other stakeholders of our intent to exercise enforcement discretion with respect to the sale and distribution of certain products that contain N-acetyl-L-cysteine (NAC)[2] and are labeled as dietary supplements. As described below, the enforcement discretion policy applies to products that would be lawfully marketed dietary supplements if NAC were not excluded from the

Education Initiatives

- Supplement Your Knowledge
  - Consumers – Education regarding claims, adverse events, and communicating with you doctor
  - Healthcare Professionals – Collaboration with the American Medical Association
  - Supplement Your Knowledge: https://www.fda.gov/food/information-consumers-using-dietary-supplements/supplement-your-knowledge
- Educators – High School Curriculum

ODSP Priorities

- Our three strategic priorities align with reasonable consumer expectations:

- Consumer safety
  - Expectation: this product will not cause illness, injury, or death

- Product integrity
  - Expectation: this product contains what the label says, in the fair amounts, and nothing else

- Informed decision-making
  - Expectation: there is some scientific basis to believe that this product will have the effect that it claims

Thank You

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