DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1497]

Toxicological Principles for the Safety Assessment of Food Ingredients; Public Meeting on Updates and Safety and Risk Assessment Considerations; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing a public meeting to solicit comments on certain topics related to our guidance titled ''Toxicological Principles for the Safety Assessment of Food Ingredients,'' known less formally as the ''Redbook.'' The purpose of our public meeting is to invite public input into possibly expanding the scope of the Redbook to include chemical safety assessments for all products over which FDA's Center for Food Safety and Applied Nutrition (CFSAN) has statutory authority including regulatory contexts such as food additives, food contact substances, dietary supplement ingredients, food contaminants, and cosmetics. The Redbook would describe toxicological principles which apply across regulatory categories while still providing specific guidance for applying these principles within each particular context. The safety of foods containing microbial contaminants will continue to remain outside of the scope of the Redbook.

DATES: See section III, ''How to Participate in the Public Meeting,'' in the **SUPPLEMENTARY INFORMATION** section of this document for the date and time of the public meeting, closing dates for advance registration, and information on deadlines for submitting either electronic or written comments to FDA's Division of Dockets Management.

ADDRESSES: See section III, ''How To Participate in the Public Meeting,'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT:

For questions about registering for the meeting; to register by telephone; or to register by mail, FAX, or email: Courtney Treece, Planning Professionals Ltd., 1210 W. McDermott St., Suite 111, Allen, TX 75013, 704–258–4983, FAX: 469–854–6992, email: *ctreece@planningprofessionals.com.*

For general questions about the meeting or for special accommodations due to a disability: Jeremiah Fasano, Center for Food Safety and Applied Nutrition (HFS–255), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1173, email: *jeremiah.fasano@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The guidance titled ''Toxicological Principles for the Safety Assessment of Food Ingredients,'' or ''Redbook,'' (*http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/ucm2006826.htm*) provides guidance to industry and other stakeholders (e.g., academia and other regulatory groups) regarding the information used by CFSAN to evaluate the safety of food and color additives. The Federal Food, Drug, and Cosmetic Act (the FD&C Act) requires our premarket approval of the use of a new food or color additive, including the new use of an approved additive. With respect to premarket approval, the safety of food additives and color additives used in foods must be established by evaluating the probable exposure to the substance and appropriate toxicological and other safety information. Thus, approval of any new food additive or color additive used in foods depends, in part, upon the outcome of toxicity tests that are performed and evaluated before marketing. The law also allows a manufacturer to market a substance for a use without premarket approval, if the substance is generally recognized as safe (GRAS). However, general recognition of safety based upon scientific procedures requires the same quantity and quality of evidence as is required to obtain food additive approval (21 CFR 170.30(b)). The same toxicological principles apply to other types of cosmetic and food safety assessments, such as for contaminants and for dietary ingredients in dietary supplements. However, the kind of information needed varies depending on the product types based on the requirements of the FD&C Act.

The Redbook sets out a system of tiered recommendations for additives in foods. These recommendations provide guidance on how much toxicity testing should be done depending on the level of estimated exposure to a substance in foods. The Redbook is a guidance document that is intended to help interested parties understand FDA's expectations regarding:

- Determining the human exposure that will occur from the use of the ingredient in foods;
- Determining which toxicity studies are appropriate;
- Designing, conducting, and reporting the results of toxicity studies; and
- Submitting the information to FDA as part of a safety assessment.

Subsequent to the Redbook's publication, we provided a related guidance document titled ''Guidance for Industry: Preparation of Food Contact Notifications for Food Contact Substances: Toxicology Recommendations'' (*http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm081825.htm*) describing the information we expect in various types of submissions concerning the safety of substances added to foods, such as food contact substances (formerly known as indirect food additives), substances generally recognized as safe for a defined use in foods, and new dietary ingredients in dietary supplement products. This related guidance document illustrates how the Redbook, developed for food additive and color additive premarket reviews, can inform assessments in other regulatory contexts, including risk assessments of constituent residues.

II. Purpose and Scope of the Public Meeting:

The purpose of this public meeting is to invite public comment on what should be included, changed, or even excluded from the updated Redbook. We are interested in expanding the scope of the Redbook to emphasize the principles of safety and risk assessment that are shared across different regulatory contexts for foods and cosmetics, while still providing specific guidance for applying these principles in particular contexts such as the requirements for pre-market safety submissions or for risk assessments conducted on foods and cosmetics already on the market. We invite comments from interested parties on the following topics:

1. What components of the Redbook should receive priority for review and update?

2. What aspects of the safety and risk assessment of food ingredients or other CFSAN-regulated products are not addressed and should be considered for incorporation in the Redbook?

3. How can the Redbook be updated to more fully support the development and submission of safety assessments for substances introduced into food?

4. How should we balance the desire for transparency and consistency in risk assessment as described in the Redbook, with the goal of flexibility in applying the most appropriate analysis for specific contexts?

III. How To Participate in the Public Meeting

We are holding the public meeting to invite public comment on what should be included, changed, or even excluded from the updated Redbook. Due to limited space and time, we encourage all persons who wish to attend the meeting to register in advance. There is no fee to register for the public meeting, and registration will be on a first-come, first-served basis. Early registration is recommended because seating is limited. Onsite registration will be accepted, as space permits, after all preregistered attendees are seated. Live Webcasting of the event is also being offered through the registration process.

Those requesting an opportunity to make an oral presentation during the time allotted for public comment at the meeting are asked to submit a request. When submitting a request to make an oral presentation, individuals should identify the number of each question they wish to address (see II. Purpose and Scope of the Public Meeting) in their presentation to help us organize the presentations. We would like to maximize the number of individuals who make a presentation at the meeting. If time permits, individuals or organizations that did not register in advance may be granted the opportunity to make an oral presentation.

We encourage persons and groups who have similar interests to consolidate their information for presentation by a single representative. After reviewing the presentation requests, we will notify each participant before the meeting of the approximate time their presentation is scheduled to begin.

While oral presentations from specific individuals and organizations will be necessarily limited due to time constraints during the public meeting, stakeholders may submit electronic or written comments discussing any issues of concern to the administrative record (the docket).

Table 1 of this document provides information on participation in the public meeting:

TABLE 1—INFORMATION ON PARTICIPATION IN THE MEETING AND ON SUBMITTING COMMENTS TO THE RULEMAKING DOCKETS

	Date	Electronic address	Address
Public meeting	December 9, 2014	*http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm.*	Wiley Building, 5100 Paint Branch Pkwy., College Park, MD 20740.
Advance registration	By December 2, 2014	Individuals who wish to participate in person are asked to preregister at *http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm.*	We encourage you to use electronic registration if possible.[1]
Request to make an oral presentation.	By November 21, 2014.	*http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm*[2].	
Request special accommodations due to a disability.	By November 21, 2014.	Jeremiah Fasano, email: *Jeremiah.Fasano@fda.hhs.gov.*	See **FOR FURTHER INFORMATION CONTACT**.
Submit electronic or written comments.	By February 9, 2015 ..	Docket FDA–2014–N–1497	Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

IV. Request for Comments

Regardless of attendance at the public meeting, interested persons may submit either electronic comments to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. To ensure consideration, submit comments by February 9, 2015. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

V. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (see **ADDRESSES**). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: October 27, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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[1] You may also register via telephone, email, mail, or FAX. Please include your name, title, firm name, address, and phone and FAX numbers in your registration information and send to: Courtney Treece, Planning Professionals Ltd., 1210 W. McDermott St., Suite 111, Allen, TX 75013, 704–258–4983, FAX: 469–854–6992, email: *ctreece@planningprofessionals.com.* Onsite registration will also be available.

[2] You may also request to make an oral presentation at the public meeting via email. Please include your name, title, firm name, address, and phone and FAX numbers and send to: Jeremiah Fasano,, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1173, email: *Jeremiah.Fasano@fda.hhs.gov.*