



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-4625]

Development of a List of Pre-Dietary Supplement Health and Education Act Dietary Ingredients; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the following public meeting entitled "Development of a List of Pre-DSHEA Dietary Ingredients." The purpose of the meeting is to give interested stakeholders an opportunity to discuss issues related to FDA's future development of such a list.

DATES: The public meeting will be held on October 3, 2017, from 8 a.m. to 5 p.m. Submit either electronic or written comments on this public meeting by December 4, 2017. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public meeting will be held at FDA's Center for Food Safety and Applied Nutrition, Wiley Auditorium, 5001 Campus Dr., College Park, MD 20740.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 4, 2017. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of December 4, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2017-N-4625 for “Development of a List of Pre-DSHEA Dietary Ingredients; Public Meeting; Request for Comments.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Juanita Yates, Center for Food Safety and Applied Nutrition (HFS-009), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1731, email: Juanita.yates@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the *Federal Register* of August 12, 2016 (81 FR 53486), we issued a notice announcing the availability of a revised draft guidance for industry entitled, “Dietary Supplements: New Dietary Ingredient Notifications and Related Issues.”¹ The revised draft guidance, when finalized, will help industry in evaluating whether to submit a premarket safety notification for a new dietary ingredient (NDI), or for a dietary supplement containing an NDI, and in preparing such premarket safety notifications (also referred to as NDI notifications). The Dietary Supplement Health and Education Act of 1994 (DSHEA) (Pub. L. 103-417) amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding, among other provisions: (1) Section 201(ff) of the FD&C Act (21 U.S.C. 321(ff)), which defines the term “dietary supplement” and (2) section 413 of the FD&C Act (21 U.S.C. 350(b)), which describes requirements for NDIs. Under DSHEA, dietary ingredients marketed in the United States before October 15, 1994, are not NDIs and therefore are not subject to the premarket notification

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<https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/dietarysupplements/ucm257563.htm>

requirements in section 413 of the FD&C Act. The revised draft guidance addressed, among other things, considerations related to determining when a dietary ingredient is not new and therefore does not require a NDI notification.

In the revised draft guidance, we stated our willingness to compile an authoritative list of pre-October 15, 1994, dietary ingredients based on independent and verifiable data to be supplied by industry. Although we are aware that several trade associations and industry groups have independently developed their own unofficial lists of ingredients that they believe were marketed before October 15, 1994 (sometimes referred to as “grandfathered” or “old” dietary ingredients), we are unable to verify the accuracy of those lists and therefore have never recognized or sanctioned any of them. We also have never compiled our own list.

An authoritative list would provide benefits to both industry and FDA. By providing clarity as to which ingredients do not require notifications, it would alleviate the burden on industry of preparing and submitting unnecessary notifications. Similarly, by eliminating unnecessary notifications, an authoritative list would enable us to more efficiently use our limited resources to review notifications for truly “new” ingredients. In addition, an authoritative list would allow us to better focus our enforcement efforts in alignment with our strategic priorities of consumer safety, product integrity, and accurate information.

We have received and are reviewing comments on the 2016 revised draft guidance. The comments generally support the idea that we should develop a list of pre-DSHEA dietary ingredients, but reflect opinions both on the standard of evidence for demonstrating that an ingredient is pre-DSHEA and on the process by which ingredients should be added to the list. We believe that public discussion of these issues will be beneficial as we work toward development of a list of pre-DSHEA dietary ingredients.

II. Topics for Discussion at the Public Meeting

The public meeting will have two separate panels. Each panel will be followed by an opportunity for open public comment. In addition, there will be an opportunity for interested stakeholders to submit additional written comments following the meeting.

The first panel will discuss what standard of evidence is necessary to determine that an ingredient was marketed before October 15, 1994. This panel may address, among other things, what types and quantity of evidence may suffice to demonstrate that a dietary ingredient was marketed in the United States prior to October 15, 1994, as well as how specifically or generally an ingredient on the list may be identified depending on the evidence presented for that ingredient. In addition, this discussion may also address whether certain botanical preparations can be accepted as “old” if the plant is demonstrated to be “old,” and whether certain classes of ingredients can be considered “old” based on common documentation. During the open comment period following this first panel, we will specifically invite comment about whether there are any considerations specific to certain classes or types of ingredients that should be taken into account as we develop the list.

The second panel will discuss issues related to the process that should be used to develop the list. This includes, but is not limited to, the processes for nominating and reviewing ingredients; whether an outside panel should be convened and, if so, the composition and role of that panel; how information that is claimed to be confidential should be treated; and what the ultimate list should look like.

The topics discussed at the public meeting, both during the panel discussions and during open public comment periods, as well as written comments submitted after the meeting, will help us determine how to develop this list of old dietary ingredients.

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website: <https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm>. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public meeting must register by midnight Eastern Time on September 25, 2017. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted.

If you need special accommodations due to a disability, please contact Juanita Yates (see FOR FURTHER INFORMATION CONTACT) no later than September 18, 2017.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during a public comment session and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and request time for a joint presentation. All requests to make oral presentations must be received by September 18, 2017. We will determine the amount of time allotted to each presenter and will select and notify participants by September 25, 2017.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast. Please visit the following website to register:

<https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm>.

FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (see ADDRESSES). A link to the transcript will also be available on the Internet at <https://www.fda.gov/Food/DietarySupplements/default.htm>.

Dated: August 28, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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