I. Background

We are announcing the availability of a guidance for FDA staff and interested parties entitled ''Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act.'' We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA 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.

In the **Federal Register** of April 19, 2022 (87 FR 23181), we announced the availability of a draft guidance for FDA staff and stakeholders entitled ''Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act.'' We gave interested parties until August 17, 2022, to submit comments for us to consider before beginning work on the final version of the guidance.

This guidance finalizes the approach we generally intend to take when evaluating the public health importance of a non-listed food allergen. The guidance specifies the scientific factors and other information relevant to the labeling and production of food containing the food allergen that we generally intend to consider when evaluating the public health importance of a non-listed food allergen. It also describes our recommendations for how to identify and evaluate the body of evidence applicable to an evaluation of the public health importance of a non-listed food allergen.

Food allergy can be broadly defined as an adverse health effect arising from a specific immune response that occurs reproducibly on exposure to a given food. A food allergen is the food or component(s) (often a protein) of a food that elicits specific immunologic reactions. While many different types of food allergies have been identified, food allergies that are most studied and understood clinically are those due to immunoglobulin E antibodies (IgE) that cause the body to release inflammatory chemicals. The most severe and immediately life-threatening food allergies are those that are mediated by IgE and are capable of triggering anaphylaxis, which can be fatal. The focus of this guidance is primarily IgE-mediated food allergy. However, we recognize that food allergens acting through other mechanisms may raise public health concerns. We intend to evaluate the public health importance of these allergens on a case-by-case basis. We will also continue gathering scientific data and other information on food allergens acting through other mechanisms to help inform possible future action on these allergens, which may include future guidance or communications to the public.

In general, the regulatory framework of the FD&C Act and our regulations implementing the FD&C Act broadly apply to the production of food that is or contains a food allergen through statutory and regulatory provisions regarding: (1) food labeling; (2) food production (*e.g.,* manufacturing, processing, packing, and holding food); and (3) the safety of substances added to food. Under section 403(w) of the FD&C Act (21 U.S.C. 343(w)), a food is misbranded if it contains a major food allergen and fails to declare that major food allergen as specified on its label using the major food allergen's common or usual name. Section 201(qq)(1) of the FD&C Act (21 U.S.C. 321(qq)(1)) defines a ''major food allergen,'' in part, as any of the following: milk, eggs, fish (*e.g.,* bass, flounder, or cod), Crustacean shellfish, tree nuts (*e.g.,* almonds, pecans, or walnuts), wheat, peanuts, soybeans, and sesame.

We considered all comments received during the comment period before developing the final guidance. Some comments on the draft guidance requested that we expand the scope of the guidance to cover non-IgE-mediated food allergies and to describe the potential regulatory options available to FDA. Other comments recommended that FDA define specific targets for each evaluation factor laid out in the framework. We have modified the final guidance where appropriate. Changes to the guidance include:

- Clarifying that evidence of non-IgE-mediated reactions can be useful as supplemental data in an evaluation of the public health importance of a food allergen;
- Incorporating updated text and a revised reference to reflect the recent publication of the Food and Agricultural Organization of the United Nations and World Health Organization's Expert Committee meeting report; and
- Expanding the discussion regarding prevalence data when a food is not regularly consumed in the United States.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 10 have been approved under OMB control number 0910–0191. The collections of information in 21 CFR part 101 have been approved under OMB control number 0910–0381. The collections of information in section 403(w) of the FD&C Act have been approved under OMB control number 0910–0792. The collections of information in 21 CFR part 117 have been approved under OMB control number 0910–0751. The collections of information for Form FDA 3800 have been approved under OMB control number 0910–0645. The collections of information for Form FDA 3500 have been approved under OMB control number 0910–0291. The collections of information in 21 CFR 70.25, 71.1, 170.36, 171.1, 172, 173, 179, and 180 have been approved under OMB control number 0910–0016.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/FoodGuidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents*, or *https://www.regulations.gov*. Use the FDA websites listed in the previous sentence to find the most current version of the guidance.

Dated: December 27, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–31529 Filed 1–6–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0465, FDA–2022–D–0466, and FDA–2022–D–0467]

Draft Guidances Relating to Recommendations To Reduce the Risk of Transmission of Relevant Communicable Disease Agents and Diseases by Human Cells, Tissues, and Cellular and Tissue-Based Products; Draft Guidances for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of three

specific draft guidances for industry entitled ''Recommendations to Reduce the Risk of Transmission of Hepatitis B Virus (HBV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps);'' ''Recommendations to Reduce the Risk of Transmission of Hepatitis C Virus (HCV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps);'' and ''Recommendations to Reduce the Risk of Transmission of Human Immunodeficiency Virus (HIV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).'' These draft guidances are intended to update existing guidances and to assist establishments making donor eligibility determinations in understanding the requirements for determining donor eligibility, including donor screening and testing, for donors of HCT/Ps. These draft guidances are also intended to provide establishments making donor eligibility determinations with recommendations to reduce the risk of transmission of specific communicable disease agents and diseases, specifically, hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV), by HCT/Ps.

DATES: Submit either electronic or written comments on the draft guidances by February 6, 2025 to ensure that the Agency considers your comment on these draft guidances before it begins work on the final versions of the guidances.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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 dockets 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–2022–D–0465 for ''Recommendations to Reduce the Risk of Transmission of Hepatitis B Virus (HBV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Draft Guidance for Industry;'' Docket No. FDA–2022–D–0466 for ''Recommendations to Reduce the Risk of Transmission of Hepatitis C Virus (HCV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Draft Guidance for Industry;'' and Docket No. FDA–2022–D–0467 for ''Recommendations to Reduce the Risk of Transmission of Human Immunodeficiency Virus (HIV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Draft Guidance for Industry.'' Received comments will be placed in the dockets 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, 240–402–7500.

- 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.'' The Agency will review this copy, including the claimed confidential information, in its 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.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the dockets to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket numbers, 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, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidances to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidances may also be obtained by phone by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidances.

FOR FURTHER INFORMATION CONTACT: Victoria Wagman, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of three draft guidances entitled: ''Recommendations to Reduce the Risk of Transmission of Hepatitis B Virus (HBV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps);'' ''Recommendations to Reduce the Risk of Transmission of Hepatitis C Virus (HCV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps);'' and ''Recommendations to Reduce the Risk

of Transmission of Human Immunodeficiency Virus (HIV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).'' When finalized, these draft guidances will update existing guidance documents and assist establishments making donor eligibility determinations in understanding the requirements for determining donor eligibility, including donor screening and testing, for donors of HCT/Ps. When finalized, these specific draft guidances will also provide establishments making donor eligibility determinations with recommendations to reduce the risk of transmission of HBV, HCV, and HIV by HCT/Ps. Updates to existing guidance recommendations include but are not limited to: revising recommendations for donor screening that includes reducing certain time-based risk factors and conditions; assessing HCT/P donor eligibility using the same individual risk-based questions relevant to risk for every donor regardless of sex or gender, and for the draft guidance related to HIV, donor testing and screening for HIV–1 group O risk.

Based on FDA review of the available science, adequacy of available test methods, studies used to evaluate risk behaviors, and experiences with updated blood donor screening questions, FDA also recommends eliminating the HCT/P donor screening questions specific to men who have sex with men (MSM) and women who have sex with MSM and, instead recommends assessing HCT/P donor eligibility using the same individual risk-based questions relevant to HBV, HCV, and HIV risk for every donor regardless of sex or gender.

TABLE 1—THREE DRAFT GUIDANCES ISSUED FOR PUBLIC COMMENT

Docket No.	Draft guidance document title
FDA–2022–D–0465.	Recommendations to Reduce the Risk of Transmission of Hepatitis B Virus (HBV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Draft Guidance for Industry.
FDA–2022–D–0466.	Recommendations to Reduce the Risk of Transmission of Hepatitis C Virus (HCV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Draft Guidance for Industry.
FDA–2022–D–0467.	Recommendations to Reduce the Risk of Transmission of Human Immunodeficiency Virus (HIV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Draft Guidance for Industry.

At a later date, FDA intends to issue additional specific draft guidances with recommendations regarding specific communicable disease agents and diseases for donors of HCT/Ps as follows: (1) transmissible spongiform encephalopathy, (2) *Treponema pallidum* (syphilis), (3) *Chlamydia trachomatis* and *Neisseria gonorrhoeae,* (4) vaccinia virus, (5) West Nile virus, (6) human T-lymphotropic virus, (7) Cytomegalovirus, and (8) communicable disease risks associated with xenotransplantation.

The draft guidances, when finalized, are intended to supersede information regarding HBV, HCV, and HIV risk in the document entitled ''Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps), Guidance for Industry,'' dated August 2007. Regarding HBV risk, the draft guidance is also intended to supersede the document entitled ''Use of Nucleic Acid Tests to Reduce the Risk of Transmission of Hepatitis B Virus from Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products, Guidance for Industry'' dated August 2016.

The three draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These draft guidances, when finalized, will represent the current thinking of FDA on ''Recommendations to Reduce the Risk of Transmission of Hepatitis B Virus (HBV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps);'' ''Recommendations to Reduce the Risk of Transmission of Hepatitis C Virus (HCV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps);'' and ''Recommendations to Reduce the Risk of Transmission of Human Immunodeficiency Virus (HIV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).'' They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While these guidances contains no new collection of information, they do refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 1271.50 have been approved under OMB control number 0910–0139.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 26, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–31523 Filed 1–6–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0464]

Recommendations for Determining Eligibility of Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance document entitled ''Recommendations for Determining Eligibility of Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).'' This draft guidance document includes general information on determining eligibility for donors of HCT/Ps. In addition, FDA intends to issue separate guidance documents with recommendations regarding reducing the risk of transmission of specific communicable disease agents and diseases for donors of HCT/Ps. These guidance documents are intended to update an existing guidance.

DATES: Submit either electronic or written comments on the draft guidance by February 6, 2025 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the